

US3352072 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:38:03

All time stamps listed in this document are displayed in GMT

US3352072

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

[Participant ID](#)

US3352072

---

[mRNA-1273-P301 Completion Guidelines](#)

---

---

US3352072

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	13 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
------------	------

US3352072

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3352072

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3352072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3352072

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3352072

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	



US3352072

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3352072

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3352072

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Condition	TUMMY TUCK
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3352072

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:45
Height (xxx.x)	163 cm
Weight (xxx.x)	72.0 kg
BMI (xxx.x)	27.09925 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352072

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Date of assessment (dd MMM yyyy) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☒  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2007

Date of last menstruation unknown False

US3352072

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

---

**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

---

**Specify**

---

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3352072

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	



US3352072

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	13 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
------------	--------

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103852

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Height	ND - Not Done
Weight	ND - Not Done

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:31
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3352072

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 13:01

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3352072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	13 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	12:36 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	13 AUG 2020 12:36
------------------------------------	-------------------



US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:02	13 AUG 2020 12:02
Nasopharyngeal Swab 2	No		

US3352072

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 AUG 2020 13:38

PC Open Date & Time

13 AUG 2020 13:21

PC Close Date & Time

13 AUG 2020 15:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	14 AUG 2020 08:12
PC Open Date & Time	13 AUG 2020 16:46
PC Close Date & Time	14 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 00:45

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 22:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

16 AUG 2020 22:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

17 AUG 2020 22:01

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

18 AUG 2020 21:49

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 AUG 2020 22:02

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 8

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	101.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	20 AUG 2020 22:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 9

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 22:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 10

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	22 AUG 2020 21:56
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 11

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 AUG 2020 22:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 12

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 AUG 2020 21:28

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 13

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	25 AUG 2020 22:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 14

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	26 AUG 2020 22:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 15

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	27 AUG 2020 21:53
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 16

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 AUG 2020 21:37

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 17

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	29 AUG 2020 21:51
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 18

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	30 AUG 2020 23:31
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 19

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	31 AUG 2020 22:00
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 20

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	01 SEP 2020 22:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 21

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred False

To **PREVENT** pain or fever from occurring True

PC Time Stamp 02 SEP 2020 21:45

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 22

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True
PC Time Stamp	03 SEP 2020 21:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 23

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	04 SEP 2020 22:00
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 24

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	05 SEP 2020 20:44
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 25

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	06 SEP 2020 21:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 26

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 SEP 2020 06:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 13:38

PC Open Date & Time

13 AUG 2020 13:21

PC Close Date & Time

13 AUG 2020 15:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 08:13

PC Open Date & Time

13 AUG 2020 16:46

PC Close Date & Time

14 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 00:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 22:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 22:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 22:01

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 21:49

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 22:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:39
PC Open Date & Time	13 AUG 2020 13:21
PC Close Date & Time	13 AUG 2020 15:51

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 08:14
PC Open Date & Time	13 AUG 2020 16:46
PC Close Date & Time	14 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

65 of 2690

EAB) (1725)

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 00:46
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

**DAY 3**

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 22:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

69 of 2690

EAB) (1725)

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

71 of 2690

EAB) (1725)



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 22:02
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

73 of 2690

EAB) (1725)

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:50
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☒

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

75 of 2690

EAB) (1725)

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:05
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☒

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 22:02

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 21 AUG 2020 22:01

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:57

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 22:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 21:28

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 25 AUG 2020 22:01

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 26 AUG 2020 22:01

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 21:53

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:37

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 20 AUG 2020 22:02

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp	21 AUG 2020 22:02
---------------	-------------------

PC Open Date & Time	21 AUG 2020 12:00
---------------------	-------------------

PC Close Date & Time	22 AUG 2020 11:59
----------------------	-------------------

---



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 22 AUG 2020 21:57

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

---

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 AUG 2020 22:03

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 24 AUG 2020 21:29

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 25 AUG 2020 22:02

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(14)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

26 AUG 2020 22:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 AUG 2020 21:53

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 28 AUG 2020 21:37

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(17)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp	29 AUG 2020 21:51
---------------	-------------------

PC Open Date & Time	29 AUG 2020 12:00
---------------------	-------------------

PC Close Date & Time	30 AUG 2020 11:59
----------------------	-------------------

---



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 AUG 2020 23:31

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(19)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

31 AUG 2020 22:00

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

---

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(20)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

01 SEP 2020 22:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

---

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(21)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

02 SEP 2020 21:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

---

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(22)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

03 SEP 2020 21:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(23)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

04 SEP 2020 22:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 24

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 SEP 2020 20:44

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(25)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 SEP 2020 21:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(26)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

08 SEP 2020 06:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

PC Time stamp 20 AUG 2020 22:03

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity ☐  
not requiring medical attention

Prevents daily activity and ☐  
requires medical attention

---

PC Open Date & Time	21 AUG 2020 12:00
---------------------	-------------------

PC Close Date & Time	22 AUG 2020 11:59
----------------------	-------------------

PC Time stamp	21 AUG 2020 22:02
---------------	-------------------

---

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity ☐  
not requiring medical attention

Prevents daily activity and ☐  
requires medical attention

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

PC Time stamp 22 AUG 2020 21:57

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 22:03
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	21 AUG 2020 22:02
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 10

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

22 AUG 2020 21:57

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 11

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

23 AUG 2020 22:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 12

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

24 AUG 2020 21:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 13

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

25 AUG 2020 22:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	26 AUG 2020 22:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	27 AUG 2020 21:53
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 16

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

28 AUG 2020 21:37

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 17
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	29 AUG 2020 21:51
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 18

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

30 AUG 2020 23:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 19

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

31 AUG 2020 22:00

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

---

**TIMEPOINT**

DAY 20

---

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

---

PC Time stamp

01 SEP 2020 22:01

---

PC Open Date & Time

01 SEP 2020 12:00

---

PC Close Date & Time

02 SEP 2020 11:59

---

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 21

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

02 SEP 2020 21:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 22

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

03 SEP 2020 21:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 23

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

04 SEP 2020 22:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 24

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

05 SEP 2020 20:44

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT

DAY 25

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☐

Yes ☒

PC Time stamp

06 SEP 2020 21:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 26
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 SEP 2020 06:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3352072

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352072

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352072

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT2

US3352072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	

US3352072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	



US3352072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Confirmed COVID-19 <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	_____
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____

**US3352072**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:03**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

US3352072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:03

Collection date ( <i>dd MMM yyyy</i> )			
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3352072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352072

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3352072

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352072

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	06 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
------------	--------

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	06:45 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 06:45
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	08:56 (24 HR)
Collection date and time (derived)	06 OCT 2020 08:56

US3352072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 14:18:16
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 OCT 2020 21:20:01

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 12:23:23
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 10:09:59
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 13:18:19
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:00:36
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

09 DEC 2020 09:41:24

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 06:32:31
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 10:05:38
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 DEC 2020 11:28:13

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 09:17:49
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 16:36:11
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 JAN 2021 21:39:46

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 JAN 2021 08:35:50

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 JAN 2021 21:09:09

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 08:14:50
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 FEB 2021 12:00:31

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 194

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 FEB 2021 06:51:13

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 FEB 2021 05:08:25

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

08 MAR 2021 23:44:45

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 MAR 2021 10:08:12

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 MAR 2021 01:05:43

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 MAR 2021 08:37:02

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 16:30:14
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 APR 2021 01:13:47

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 APR 2021 00:59:08

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 APR 2021 17:41:07

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

<b>TIMEPOINT</b>	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 18:41:14
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 JUN 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JUL 2021 23:59

---



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 341

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 JUL 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 AUG 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 SEP 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 460

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 FEB 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 MAR 2022 23:59

---



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAR 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 MAY 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 JUN 2022 23:59

---



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 JUN 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59



US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

---

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3352072

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:38:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 21:09:38

US3352072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3352072

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352072

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352072

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352072

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 11:04:44

Generated On: 11 Aug 2021 22:38:03

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT4



US3352072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3352072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

US3352072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:37:09

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352072

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3352072**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3352072**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Date of Contact	21 AUG 2020
Time of Contact	10:45
Date and Time of Contact (derived)	21 AUG 2020 10:45
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.8 C
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.4 F
-------------	---------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2690



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

398 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

402 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

406 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

414 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

422 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

426 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

430 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

434 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

438 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Date of Visit	21 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	21 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

446 of 2690

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

447 of 2690



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 AUG 2020
Day 5	Yes	25 AUG 2020
Day 7	Yes	27 AUG 2020
Day 9	Yes	29 AUG 2020
Day 14	Yes	03 SEP 2020
Day 21	Yes	10 SEP 2020
Day 28	Yes	17 SEP 2020

US3352072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	21 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
------------	--------

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:50
Height (xxx.x)	163.0 cm
Weight (xxx.x)	72.0 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

21 AUG 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3352072

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 AUG 2020

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28



US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:21
Height (xxx.x)	163.0 cm
Weight (xxx.x)	73.0 kg
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 SEP 2020

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	13 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 FEB 2021

Collection time (00:00-23:59)

13:57 (24 HR)

Collection date and time (derived)

13 FEB 2021 13:57

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	13 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	13:45
---------------------------------	-------

Collection Date and Time (derived)	13 FEB 2021 13:45
------------------------------------	-------------------

US3352072

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

AEID	USA-US066-2020-MRNA-1273-P30 1000001
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

464 of 2690

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

SUBJECT CAME INTO THE SITE  
ON 8/21/2020 COMPLAINING OF  
COVID-19 SYMPTOMS. SUBJECT  
WAS TEST AND RESULTS  
CONFIRMED SUBJECT WAS  
POSITIVE. SHE STATED SHE  
TOOK TYLENOL AND MUCINEX  
DM FOR SYMPTOMS OF COUGH  
AND BODY ACHES. SYMPTOMS  
EXHIBITED ARE CHILLS,  
COUGH, FATIGUE, MUSCLE  
ACHES, BODY ACHES,  
HEADACHES, LOSS OF TASTE,  
LOSS OF SMELL, CONGESTION,  
RUNNY NOSE, AND DIARRHEA.  
SUBJECT HAS NOT REQUIRED  
MEDICAL INTERVENTION NOR  
SURGICAL TREATMENTS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

---

---

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES (DUE TO COVID-19)

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

468 of 2690

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication COUGH (DUE TO COVID-19)

Dose per administration 600

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

470 of 2690

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

472 of 2690

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:38:03

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3352072

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:38:03

Date of dosing discontinuation (dd MMM yyyy) 21 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3352072

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:38:03

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

SAEID	USA-US066-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

SAEID	USA-US066-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/AUG/2020 17:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

SAEID	USA-US066-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/SEP/2020 18:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:36:46

Generated On: 11 Aug 2021 22:38:03

SAEID	USA-US066-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/OCT/2020 15:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3352072 (Prod: Research Centers of America - ERG)

US3352072

Form: Participant Creation

Generated On: 11 Aug 2021 22:38:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'US3352072'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:36

US3352072

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:19:29

US3352072

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:22
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:37

US3352072

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 18:19:29

**US3352072**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'SCRN'	System	13 Aug 2020 18:19:29

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:37



US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '63'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

**US3352072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:03**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'YEARS'	System	13 Aug 2020 18:19:45

**US3352072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:03**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '63'	System	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered 'Female (F)'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered 'l'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45



US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:19:45

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered '13 Aug 2020'	Sara Gomez (b) (4)	13 Aug 2020 17:33:48
	(b) (4)	

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Aug 2020'	System	13 Aug 2020 17:33:48



US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '2020'	System	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered 'Amendment 2 (2)'	Sara Gomez (b) (4)	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered 'Yes (Y)'	Sara Gomez (b) (4)	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:33:48
	(b) (4)	

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered 'No (N)'	Sara Gomez (b) (4)	13 Aug 2020 17:33:48

US3352072

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:02:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:14:37

**US3352072**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:03**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1'	System	13 Aug 2020 17:33:57



US3352072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:38:03

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:03:02
User entered 'Yes (Y)'	Sara Gomez (b) (4)	13 Aug 2020 17:33:57
	(b) (4)	

US3352072

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:38:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:19:55

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 21:26:11
User closed query 'please consider changing to a medical diagnosis: Presbyopia' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 21:25:50
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 13:29:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 13:29:52
Data point term sent to Coder	System	30 Oct 2020 13:28:58
Query 'please consider changing to a medical diagnosis: Presbyopia' answered with 'data updated' (Site from CRA).	Matthew Muniz (b) (4)	30 Oct 2020 13:28:45
Coding entries removed.	Matthew Muniz (b) (4)	30 Oct 2020 13:28:36
User entered 'presbyopia' reason for change: New Information	Matthew Muniz (b) (4)	30 Oct 2020 13:28:36
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:59
DataPoint Verified.		29 Oct 2020 18:05:58
User opened query 'please consider changing to a medical diagnosis: Presbyopia' (Site from CRA).		29 Oct 2020 18:05:54
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:26:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:26:24
Data point term sent to Coder	System	13 Aug 2020 18:25:24
User entered 'Reading Glasses'	(b) (4), (b) (6)	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'un UNK 1997'	(b) (4), (b) (6)	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:24:46



US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 1997'	System	13 Aug 2020 18:24:46

**US3352072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1997'	System	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered empty.	System	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:03

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered empty.	System	13 Aug 2020 18:24:46

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:27:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:27:31
Data point term sent to Coder	System	13 Aug 2020 18:26:28
User entered 'postmenopausal'	(b) (4), (b) (6)	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User closed query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:26:03
Query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' answered with 'Data for last menstruation was updated' (Site from DM).	Wanda Delgado (b) (4)	13 Oct 2020 19:33:29
User opened query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:05:13
User entered 'un UNK 2007'	(b) (4), (b) (6)	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:25:55



US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 2007'	System	13 Aug 2020 18:25:55

**US3352072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '2007'	System	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:03

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered empty.	System	13 Aug 2020 18:25:55

**US3352072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered empty.	System	13 Aug 2020 18:25:55

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:29:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:29:21
Data point term sent to Coder	System	13 Aug 2020 18:28:34
User entered 'C-section'	(b) (4), (b) (6)	13 Aug 2020 18:28:04

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'un UNK 1979'	(b) (4), (b) (6)	13 Aug 2020 18:28:04



US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:28:04

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:28:04

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'UN UNK 1979'	(b) (4), (b) (6)	13 Aug 2020 18:28:04

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:28:04

US3352072

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 1979'	System	13 Aug 2020 18:28:04

**US3352072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1979'	System	13 Aug 2020 18:28:04

**US3352072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 1979'	System	13 Aug 2020 18:28:04

**US3352072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1979'	System	13 Aug 2020 18:28:04



US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominoplasty, LLT: Tummy tuck - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:30:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:30:23
Data point term sent to Coder	System	13 Aug 2020 18:29:38
User entered 'Tummy tuck'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:05:58
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:28:50

**US3352072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 2000'	System	13 Aug 2020 18:28:50

**US3352072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '2000'	System	13 Aug 2020 18:28:50



US3352072

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:03

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'Jan 2000'	System	13 Aug 2020 18:28:50

**US3352072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '2000'	System	13 Aug 2020 18:28:50

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered '11:45'	(b) (4), (b) (6)	13 Aug 2020 18:21:28

**US3352072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 11:45'	System	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered '163' cm	(b) (4), (b) (6)	13 Aug 2020 18:21:28
DataPoint set to visible.	System	13 Aug 2020 17:33:57

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered '72.0' kg	(b) (4), (b) (6)	13 Aug 2020 18:21:28
DataPoint set to visible.	System	13 Aug 2020 17:33:57



US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
Amendment Manager: User entered '27.09925'	System	16 Sep 2020 23:55:25
User entered '27.1'	System	13 Aug 2020 18:21:28
DataPoint set to visible.	System	13 Aug 2020 17:33:57

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'kg/m2'	System	13 Aug 2020 18:21:28
DataPoint set to visible.	System	13 Aug 2020 17:33:57

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 10:44:26
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:21:34
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:21:28
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'bpm'	System	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:21:28



US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'breaths/min'	System	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:21:28

**US3352072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:21:28

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23

US3352072

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23

US3352072

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:21:49



US3352072

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:30
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:21:49

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User closed query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:32:52
Query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' answered with 'Data updated ' (Site from DM).	Wanda Delgado (b) (4)	13 Oct 2020 19:32:07
User entered 'UN UNK 2007' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:31:58
User opened query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:40:59
User entered 'un UNK 1997'	(b) (4), (b) (6)	13 Aug 2020 18:23:09



US3352072

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:03

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:11:37
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:09

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43



US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:23:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:23:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 18:23:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:23:43
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:23:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:23:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 18:23:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:23:43
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43



US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:23:43

US3352072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:29:18

US3352072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:29:18



US3352072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 18:29:18

US3352072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'VISIT1'	System	13 Aug 2020 18:29:18

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:32

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:12:05
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:12:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:49:32
User entered '103852' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:32

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:32

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:29:29

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:29:29

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:29:29



US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:29:29

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:29:29

US3352072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:03

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:34:10
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	03 Nov 2020 20:57:43
User entered 'No (N)'	Matthew Muniz (b) (4)	03 Nov 2020 20:57:35
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:29:14
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:02:30

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '163' cm	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '72.0' kg	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '163' cm	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '72.0' kg	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05



US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '11:45'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 11:45'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '36.6' C	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '60'	(b) (4), (b) (6)	13 Aug 2020 18:32:05



US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'bpm'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '14'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'breaths/min'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '128'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '72'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '163' cm	(b) (4), (b) (6)	13 Aug 2020 18:32:05



US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 22:18:04
User entered '72.0' kg	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 05:28:48
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data confirmed. Procedure to be completed 30min post dose. ' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:32:34
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 18:32:05
User entered '13:31'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 13:31'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '36.8' C	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 18:32:05



US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '57'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'bpm'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '14'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'breaths/min'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '134'	(b) (4), (b) (6)	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '71'	(b) (4), (b) (6)	13 Aug 2020 18:32:05



US3352072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'mmHg'	System	13 Aug 2020 18:32:05

US3352072

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	Wanda Delgado (b) (4)	13 Aug 2020 20:25:39

US3352072

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	Wanda Delgado (b) (4)	13 Aug 2020 20:25:39

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	Sara Gomez (b) (4)	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	Sara Gomez (b) (4)	13 Aug 2020 17:34:50



US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13:01'	Sara Gomez (b) (4)	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 13:01'	System	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Right Arm (RIGHT ARM)'	Sara Gomez (b) (4)	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'ONCE'	System	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:34:50

US3352072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:33:15

US3352072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:33:15

US3352072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '12:36'	(b) (4), (b) (6)	13 Aug 2020 18:33:15



US3352072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 12:36'	System	13 Aug 2020 18:33:15

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered '12:02'	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '13 Aug 2020 12:02'	System	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:33:32



US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered empty.	System	13 Aug 2020 18:33:32

US3352072

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:33:36

US3352072

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1'	System	13 Aug 2020 18:33:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:37:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8d598dc5-ab54-407c-88c2-357b75ee8949' User entered 'Yes (Y)'	System	13 Aug 2020 17:38:09
	System	13 Aug 2020 17:38:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:37:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8d598dc5-ab54-407c-88c2-357b75ee8949' User entered '97.2'	System	13 Aug 2020 17:38:09
	System	13 Aug 2020 17:38:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:37:58', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8d598dc5-ab54-407c-88c2-357b75ee8949'	System	13 Aug 2020 17:38:09
User entered 'No (N)'	System	13 Aug 2020 17:38:09



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8d598dc5-ab54-407c-88c2-357b75ee8949' User entered '13 Aug 2020 13:38'	System	13 Aug 2020 17:38:09
	System	13 Aug 2020 17:38:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 13:21'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 15:51'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:10:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '06bd5c09-c127-4a48-8667-ab39e3641e67' User entered 'Yes (Y)'	System	14 Aug 2020 12:12:49
	System	14 Aug 2020 12:12:49

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:12:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '06bd5c09-c127-4a48-8667-ab39e3641e67' User entered '97.2'	System	14 Aug 2020 12:12:49
	System	14 Aug 2020 12:12:49

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:12:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '06bd5c09-c127-4a48-8667-ab39e3641e67'	System	14 Aug 2020 12:12:49
User entered 'No (N)'	System	14 Aug 2020 12:12:49

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:12:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '06bd5c09-c127-4a48-8667-ab39e3641e67'	System	14 Aug 2020 12:12:49
User entered '14 Aug 2020 08:12'	System	14 Aug 2020 12:12:49



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 16:46'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 2'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:45:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d60046c-0ff4-41e8-80a8-9135fb031e27'	System	15 Aug 2020 04:45:53
User entered 'Yes (Y)'	System	15 Aug 2020 04:45:53

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:45:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d60046c-0ff4-41e8-80a8-9135fb031e27' User entered '97.2'	System	15 Aug 2020 04:45:53
	System	15 Aug 2020 04:45:53

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:45:39', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d60046c-0ff4-41e8-80a8-9135fb031e27'	System	15 Aug 2020 04:45:53
User entered 'No (N)'	System	15 Aug 2020 04:45:53

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:45:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d60046c-0ff4-41e8-80a8-9135fb031e27' User entered '15 Aug 2020 00:45'	System	15 Aug 2020 04:45:53
	System	15 Aug 2020 04:45:53

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 3'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:01:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '54bc7e03-fa62-4801-a930-b6135c2d2a94' User entered 'Yes (Y)'	System	16 Aug 2020 02:01:47
	System	16 Aug 2020 02:01:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:01:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '54bc7e03-fa62-4801-a930-b6135c2d2a94' User entered '97.2'	System	16 Aug 2020 02:01:47
	System	16 Aug 2020 02:01:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:01:35', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '54bc7e03-fa62-4801-a930-b6135c2d2a94'	System	16 Aug 2020 02:01:47
User entered 'No (N)'	System	16 Aug 2020 02:01:47

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:01:43', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '54bc7e03-fa62-4801-a930-b6135c2d2a94' User entered '15 Aug 2020 22:01'	System	16 Aug 2020 02:01:47
	System	16 Aug 2020 02:01:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 4'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:00:31', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3de7a5d2-c078-4291-a4a9-b3a2ebab918a' User entered 'Yes (Y)'	System	17 Aug 2020 02:00:57
	System	17 Aug 2020 02:00:57

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:00:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3de7a5d2-c078-4291-a4a9-b3a2ebab918a' User entered '97.4'	System	17 Aug 2020 02:00:57
	System	17 Aug 2020 02:00:57

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:00:47', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3de7a5d2-c078-4291-a4a9-b3a2ebab918a' User entered 'No (N)'	System	17 Aug 2020 02:00:57
	System	17 Aug 2020 02:00:57

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:00:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3de7a5d2-c078-4291-a4a9-b3a2ebab918a' User entered '16 Aug 2020 22:00'	System	17 Aug 2020 02:00:57
	System	17 Aug 2020 02:00:57

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 5'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:00:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '411e571a-dce9-4a36-b27d-48700eaf42a8' User entered 'Yes (Y)'	System	18 Aug 2020 02:01:25
	System	18 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:08', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '411e571a-dce9-4a36-b27d-48700eaf42a8' User entered '97.2'	System	18 Aug 2020 02:01:25
	System	18 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:17', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '411e571a-dce9-4a36-b27d-48700eaf42a8' User entered 'No (N)'	System	18 Aug 2020 02:01:25
	System	18 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '411e571a-dce9-4a36-b27d-48700eaf42a8' User entered '17 Aug 2020 22:01'	System	18 Aug 2020 02:01:25
	System	18 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 6'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:09', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '39f3b7dd-fd2a-4f07-8be7-10453d085460' User entered 'Yes (Y)'	System	19 Aug 2020 01:49:25
	System	19 Aug 2020 01:49:25



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '39f3b7dd-fd2a-4f07-8be7-10453d085460' User entered '98.8'	System	19 Aug 2020 01:49:25
	System	19 Aug 2020 01:49:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '39f3b7dd-fd2a-4f07-8be7-10453d085460' User entered 'No (N)'	System	19 Aug 2020 01:49:25
	System	19 Aug 2020 01:49:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '39f3b7dd-fd2a-4f07-8be7-10453d085460' User entered '18 Aug 2020 21:49'	System	19 Aug 2020 01:49:25
	System	19 Aug 2020 01:49:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 7'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:01:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0' User entered 'Yes (Y)'	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:01:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0' User entered '100.5'	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:01:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0'	System	20 Aug 2020 02:02:11
User entered 'Yes (Y)'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:25:03
	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0' User entered '0'	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '23e54374-2c80-43bb-b4bc-1542e60631f0' User entered '19 Aug 2020 22:02'	System	20 Aug 2020 02:02:11
	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:02:11
User entered 'Day 8'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:00:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439' User entered 'Yes (Y)'	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:01:33', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439' User entered '101.0'	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:01:39', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439'	System	21 Aug 2020 02:01:56
User entered 'Yes (Y)'	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:01:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:25:26
	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:01:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439' User entered '0'	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:01:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ac5ded1c-63df-4eaf-9c6b-6382dbe29439' User entered '20 Aug 2020 22:01'	System	21 Aug 2020 02:01:56
	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:02:11
User entered 'Day 9'	System	20 Aug 2020 02:02:11



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8' User entered 'Yes (Y)'	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8' User entered '100.2'	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8'	System	22 Aug 2020 02:02:09
User entered 'Yes (Y)'	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8'	Wanda Delgado (b) (4)	14 Nov 2020 13:25:37
User entered '1'	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8' User entered '0'	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '27181d3c-bb08-4258-b46a-4341066a00a8' User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:09
	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 02:02:11



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	21 Aug 2020 02:01:56
User entered 'Day 10'	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443' User entered 'Yes (Y)'	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443' User entered '98.1'	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443'	System	23 Aug 2020 01:57:02
User entered 'Yes (Y)'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:30:15
	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443' User entered '0'	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:56:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7eaf3e80-5899-4f72-a0d5-40de10b21443' User entered '22 Aug 2020 21:56'	System	23 Aug 2020 01:57:02
	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:01:56



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	22 Aug 2020 02:02:09
User entered 'Day 11'	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:00:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered 'Yes (Y)'	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:01:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered '96.2'	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:01:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered 'Yes (Y)'	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:01:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:30:29
	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:01:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered '0'	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:01:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00991d47-fc33-438a-a9d2-b5da6c9d36be' User entered '23 Aug 2020 22:01'	System	24 Aug 2020 02:01:58
	System	24 Aug 2020 02:01:58



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:02:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	23 Aug 2020 01:57:02
User entered 'Day 12'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2' User entered 'Yes (Y)'	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2' User entered '98.1'	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2'	System	25 Aug 2020 01:28:47
User entered 'Yes (Y)'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:30:39
	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2' User entered '0'	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:43', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f59642b1-7f4e-45bb-861a-24003c014bf2' User entered '24 Aug 2020 21:28'	System	25 Aug 2020 01:28:47
	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	24 Aug 2020 02:01:58
User entered 'Day 13'	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:00:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308' User entered 'Yes (Y)'	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:00:58', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308' User entered '98.1'	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308'	System	26 Aug 2020 02:01:25
User entered 'Yes (Y)'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:18', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308' User entered '0'	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:05:52
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:18', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:30:51
	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '13526b9b-f0b3-4934-b6fb-ddd260724308' User entered '25 Aug 2020 22:01'	System	26 Aug 2020 02:01:25
	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	25 Aug 2020 01:28:47
User entered 'Day 14'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered 'Yes (Y)'	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered '98.2'	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered 'Yes (Y)'	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered '0'	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:15
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:31:04
	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '56c9ed3d-aaa2-4dc4-85a3-85c53aa8bd3b' User entered '26 Aug 2020 22:01'	System	27 Aug 2020 02:01:43
	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	26 Aug 2020 02:01:25
User entered 'Day 15'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:52:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435' User entered 'Yes (Y)'	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:52:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435' User entered '97.5'	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:52:54', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435'	System	28 Aug 2020 01:53:12
User entered 'Yes (Y)'	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435' User entered '0'	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:19
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:31:14
	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:08', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6545b155-20fa-43b0-ae94-e69efd918435' User entered '27 Aug 2020 21:53'	System	28 Aug 2020 01:53:12
	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	27 Aug 2020 02:01:43
User entered 'Day 16'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:36:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625' User entered 'Yes (Y)'	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:12', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625' User entered '98.0'	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625'	System	29 Aug 2020 01:37:37
User entered 'Yes (Y)'	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:31:25
	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625' User entered '0'	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c1fc2784-a96b-4d85-8676-8dbbbd069625' User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:37:37
	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	28 Aug 2020 01:53:12
User entered 'Day 17'	System	28 Aug 2020 01:53:12



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139' User entered 'Yes (Y)'	System	30 Aug 2020 01:51:31
	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139' User entered '97.0'	System	30 Aug 2020 01:51:31
	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139'	System	30 Aug 2020 01:51:31
User entered 'Yes (Y)'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:25', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 13:31:34
	System	30 Aug 2020 01:51:31
	System	30 Aug 2020 01:51:31
	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:25', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139' User entered '0'	System	30 Aug 2020 01:51:31
	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd47fe06f-6537-491c-953d-0193748b1139'	System	30 Aug 2020 01:51:31
User entered '29 Aug 2020 21:51'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:53:12



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	29 Aug 2020 01:37:37
User entered 'Day 18'	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:30:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489' User entered 'Yes (Y)'	System	31 Aug 2020 03:31:14
	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:30:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489' User entered '97.2'	System	31 Aug 2020 03:31:14
	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489' User entered 'Yes (Y)'	System	31 Aug 2020 03:31:14
	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489' User entered '0'	System	31 Aug 2020 03:31:14
	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:35
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:30:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489'	System	31 Aug 2020 03:31:14
User entered '1'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:09', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b7d989fa-3173-4b35-8b38-efdf09032489' User entered '30 Aug 2020 23:31'	System	31 Aug 2020 03:31:14
	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:37:37



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	30 Aug 2020 01:51:31
User entered 'Day 19'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76' User entered 'Yes (Y)'	System	01 Sep 2020 02:00:47
	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76' User entered '97.0'	System	01 Sep 2020 02:00:47
	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76'	System	01 Sep 2020 02:00:47
User entered 'Yes (Y)'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:31:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:39', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76'	System	01 Sep 2020 02:00:47
User entered '1'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:39', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76' User entered '0'	System	01 Sep 2020 02:00:47
	System	01 Sep 2020 02:00:47

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6cb390c-96c2-4476-8b09-89c572f85c76'	System	01 Sep 2020 02:00:47
User entered '31 Aug 2020 22:00'	System	01 Sep 2020 02:00:47



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(19)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	31 Aug 2020 03:31:14
User entered 'Day 20'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:00:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a' User entered 'Yes (Y)'	System	02 Sep 2020 02:01:09
	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:00:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a' User entered '97.1'	System	02 Sep 2020 02:01:09
	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:00:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a' User entered 'Yes (Y)'	System	02 Sep 2020 02:01:09
	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a' User entered '0'	System	02 Sep 2020 02:01:09
	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:06:52
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:31:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a'	System	02 Sep 2020 02:01:09
User entered '1'	System	02 Sep 2020 02:01:09



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f6ab3d9d-de08-41b0-a660-cb2f1338c47a' User entered '01 Sep 2020 22:01'	System	02 Sep 2020 02:01:09
	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	01 Sep 2020 02:00:47
User entered 'Day 21'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309' User entered 'Yes (Y)'	System	03 Sep 2020 01:45:36
	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309' User entered '97.0'	System	03 Sep 2020 01:45:36
	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309'	System	03 Sep 2020 01:45:36
User entered 'Yes (Y)'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309' User entered '0'	System	03 Sep 2020 01:45:36
	System	03 Sep 2020 01:45:36



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:07:07
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:32:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309'	System	03 Sep 2020 01:45:36
User entered '1'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51f9e2-67b7-46f3-a88f-8e5c9e978309'	System	03 Sep 2020 01:45:36
User entered '02 Sep 2020 21:45'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	02 Sep 2020 02:01:09
User entered 'Day 22'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5' User entered 'Yes (Y)'	System	04 Sep 2020 01:45:45
	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:35', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5' User entered '97.0'	System	04 Sep 2020 01:45:45
	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5' User entered 'Yes (Y)'	System	04 Sep 2020 01:45:45
	System	04 Sep 2020 01:45:45



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5' User entered '0'	System	04 Sep 2020 01:45:45
	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:07:12
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:32:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5'	System	04 Sep 2020 01:45:45
User entered '1'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f51a8c9-b9b2-4429-8017-7a16789d04c5' User entered '03 Sep 2020 21:45'	System	04 Sep 2020 01:45:45
	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	03 Sep 2020 01:45:36
User entered 'Day 23'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda' User entered 'Yes (Y)'	System	05 Sep 2020 02:00:51
	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda' User entered '97.2'	System	05 Sep 2020 02:00:51
	System	05 Sep 2020 02:00:51



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda' User entered 'Yes (Y)'	System	05 Sep 2020 02:00:51
	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:43', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda' User entered '0'	System	05 Sep 2020 02:00:51
	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:07:16
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:33:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:43', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda'	System	05 Sep 2020 02:00:51
User entered '1'	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '504d2267-9e3d-4046-8a86-b48af7f3dcda' User entered '04 Sep 2020 22:00'	System	05 Sep 2020 02:00:51
	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	04 Sep 2020 01:45:45
User entered 'Day 24'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111' User entered 'Yes (Y)'	System	06 Sep 2020 00:44:30
	System	06 Sep 2020 00:44:30



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111' User entered '97.5'	System	06 Sep 2020 00:44:30
	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:20', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111'	System	06 Sep 2020 00:44:30
User entered 'Yes (Y)'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111' User entered '0'	System	06 Sep 2020 00:44:30
	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:07:20
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111'	System	06 Sep 2020 00:44:30
User entered '1'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:26', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a03ca12b-d4de-4dd3-b2f6-5946d2715111' User entered '05 Sep 2020 20:44'	System	06 Sep 2020 00:44:30
	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	05 Sep 2020 02:00:51
User entered 'Day 25'	System	05 Sep 2020 02:00:51



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:46:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712' User entered 'Yes (Y)'	System	07 Sep 2020 01:47:05
	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:46:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712' User entered '97.5'	System	07 Sep 2020 01:47:05
	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:46:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712'	System	07 Sep 2020 01:47:05
User entered 'Yes (Y)'	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712' User entered '0'	System	07 Sep 2020 01:47:05
	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED AND IT WAS CONFIRMED SUBJECT TOOK MUCINEX FOR COUGH FROM 27AUG2020 - 31AUG2020. DATA WAS ENTERED IN CON MED FORM.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:08:01
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712'	System	07 Sep 2020 01:47:05
User entered '1'	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '335c576d-ca09-4ab1-8931-f995edc52712' User entered '06 Sep 2020 21:47'	System	07 Sep 2020 01:47:05
	System	07 Sep 2020 01:47:05

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 02:00:51



US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	06 Sep 2020 00:44:30
User entered 'Day 26'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:34:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f7fa44e5-46ac-475e-8673-5b3622ebd07a' User entered 'Yes (Y)'	System	08 Sep 2020 10:35:07
	System	08 Sep 2020 10:35:07

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:34:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f7fa44e5-46ac-475e-8673-5b3622ebd07a' User entered '97.2'	System	08 Sep 2020 10:35:07
	System	08 Sep 2020 10:35:07

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f7fa44e5-46ac-475e-8673-5b3622ebd07a' User entered 'No (N)'	System	08 Sep 2020 10:35:07
	System	08 Sep 2020 10:35:07

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(26)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f7fa44e5-46ac-475e-8673-5b3622ebd07a' User entered '08 Sep 2020 06:35'	System	08 Sep 2020 10:35:07
	System	08 Sep 2020 10:35:07

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:25', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20b0c32a-af13-45d0-acaa-a3784791ef23' User entered 'None (1)'	System	13 Aug 2020 17:38:51
	System	13 Aug 2020 17:38:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20b0c32a-af13-45d0-acaa-a3784791ef23' User entered 'No (N)'	System	13 Aug 2020 17:38:51
	System	13 Aug 2020 17:38:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20b0c32a-af13-45d0-acaa-a3784791ef23' User entered 'No (N)'	System	13 Aug 2020 17:38:51
	System	13 Aug 2020 17:38:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20b0c32a-af13-45d0-acaa-a3784791ef23' User entered 'None (1)'	System	13 Aug 2020 17:38:51
	System	13 Aug 2020 17:38:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20b0c32a-af13-45d0-acaa-a3784791ef23' User entered '13 Aug 2020 13:38'	System	13 Aug 2020 17:38:51
	System	13 Aug 2020 17:38:51

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 13:21'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 15:51'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:13:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2158bfb2-6ef5-4709-8298-6bd119b67493' User entered 'None (1)'	System	14 Aug 2020 12:13:48
	System	14 Aug 2020 12:13:48

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:13:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2158bfb2-6ef5-4709-8298-6bd119b67493' User entered 'No (N)'	System	14 Aug 2020 12:13:48
	System	14 Aug 2020 12:13:48

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:13:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2158bfb2-6ef5-4709-8298-6bd119b67493' User entered 'No (N)'	System	14 Aug 2020 12:13:48
	System	14 Aug 2020 12:13:48

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:13:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2158bfb2-6ef5-4709-8298-6bd119b67493' User entered 'None (1)'	System	14 Aug 2020 12:13:48
	System	14 Aug 2020 12:13:48

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:13:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2158bfb2-6ef5-4709-8298-6bd119b67493' User entered '14 Aug 2020 08:13'	System	14 Aug 2020 12:13:48
	System	14 Aug 2020 12:13:48

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 16:46'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 2'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:06', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f8808bf6-3c48-4f63-8c87-8cea1fc6944e' User entered 'None (1)'	System	15 Aug 2020 04:46:22
	System	15 Aug 2020 04:46:22

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f8808bf6-3c48-4f63-8c87-8cea1fc6944e' User entered 'No (N)'	System	15 Aug 2020 04:46:22
	System	15 Aug 2020 04:46:22

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f8808bf6-3c48-4f63-8c87-8cea1fc6944e' User entered 'No (N)'	System	15 Aug 2020 04:46:22
	System	15 Aug 2020 04:46:22

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:17', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f8808bf6-3c48-4f63-8c87-8cea1fc6944e' User entered 'None (1)'	System	15 Aug 2020 04:46:22
	System	15 Aug 2020 04:46:22

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f8808bf6-3c48-4f63-8c87-8cea1fc6944e' User entered '15 Aug 2020 00:46'	System	15 Aug 2020 04:46:22
	System	15 Aug 2020 04:46:22

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 3'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:01:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd33070f7-0122-49f3-9f28-50deca9a6a7b' User entered 'None (1)'	System	16 Aug 2020 02:02:26
	System	16 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:06', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd33070f7-0122-49f3-9f28-50deca9a6a7b' User entered 'No (N)'	System	16 Aug 2020 02:02:26
	System	16 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd33070f7-0122-49f3-9f28-50deca9a6a7b' User entered 'No (N)'	System	16 Aug 2020 02:02:26
	System	16 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:20', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd33070f7-0122-49f3-9f28-50deca9a6a7b' User entered 'None (1)'	System	16 Aug 2020 02:02:26
	System	16 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd33070f7-0122-49f3-9f28-50deca9a6a7b' User entered '15 Aug 2020 22:02'	System	16 Aug 2020 02:02:26
	System	16 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 4'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:06', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '0065a77c-cd6c-4126-a8bb-05a2ce84318f' User entered 'None (1)'	System	17 Aug 2020 02:01:29
	System	17 Aug 2020 02:01:29

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '0065a77c-cd6c-4126-a8bb-05a2ce84318f' User entered 'No (N)'	System	17 Aug 2020 02:01:29
	System	17 Aug 2020 02:01:29

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:18', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '0065a77c-cd6c-4126-a8bb-05a2ce84318f' User entered 'No (N)'	System	17 Aug 2020 02:01:29
	System	17 Aug 2020 02:01:29

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '0065a77c-cd6c-4126-a8bb-05a2ce84318f' User entered 'None (1)'	System	17 Aug 2020 02:01:29
	System	17 Aug 2020 02:01:29

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '0065a77c-cd6c-4126-a8bb-05a2ce84318f' User entered '16 Aug 2020 22:01'	System	17 Aug 2020 02:01:29
	System	17 Aug 2020 02:01:29

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 5'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f651e45-f240-4d3a-beaf-c1a9b3ee09c8'	System	18 Aug 2020 02:01:45
User entered 'None (1)'	System	18 Aug 2020 02:01:45

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:36', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f651e45-f240-4d3a-beaf-c1a9b3ee09c8'	System	18 Aug 2020 02:01:45
User entered 'No (N)'	System	18 Aug 2020 02:01:45

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f651e45-f240-4d3a-beaf-c1a9b3ee09c8'	System	18 Aug 2020 02:01:45
User entered 'No (N)'	System	18 Aug 2020 02:01:45

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f651e45-f240-4d3a-beaf-c1a9b3ee09c8'	System	18 Aug 2020 02:01:45
User entered 'None (1)'	System	18 Aug 2020 02:01:45

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7f651e45-f240-4d3a-beaf-c1a9b3ee09c8' User entered '17 Aug 2020 22:01'	System	18 Aug 2020 02:01:45
	System	18 Aug 2020 02:01:45

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 6'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '664fd168-8723-4263-8bce-aac5e37dbb55'	System	19 Aug 2020 01:49:49
User entered 'None (1)'	System	19 Aug 2020 01:49:49

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:37', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '664fd168-8723-4263-8bce-aac5e37dbb55'	System	19 Aug 2020 01:49:49
User entered 'No (N)'	System	19 Aug 2020 01:49:49

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '664fd168-8723-4263-8bce-aac5e37dbb55'	System	19 Aug 2020 01:49:49
User entered 'No (N)'	System	19 Aug 2020 01:49:49

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '664fd168-8723-4263-8bce-aac5e37dbb55'	System	19 Aug 2020 01:49:49
User entered 'None (1)'	System	19 Aug 2020 01:49:49

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:47', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '664fd168-8723-4263-8bce-aac5e37dbb55'	System	19 Aug 2020 01:49:49
User entered '18 Aug 2020 21:49'	System	19 Aug 2020 01:49:49

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 7'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'af12cf29-7aeb-4533-aeel-a488048f423a' User entered 'None (1)'	System	20 Aug 2020 02:03:08
	System	20 Aug 2020 02:03:08

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'af12cf29-7aeb-4533-aeel-a488048f423a' User entered 'No (N)'	System	20 Aug 2020 02:03:08
	System	20 Aug 2020 02:03:08

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'af12cf29-7aeb-4533-aeel-a488048f423a' User entered 'No (N)'	System	20 Aug 2020 02:03:08
	System	20 Aug 2020 02:03:08

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:02:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'af12cf29-7aeb-4533-aeel-a488048f423a'	System	20 Aug 2020 02:03:08
User entered 'None (1)'	System	20 Aug 2020 02:03:08

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:03:06', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'af12cf29-7aeb-4533-aeel-a488048f423a' User entered '19 Aug 2020 22:03'	System	20 Aug 2020 02:03:08
	System	20 Aug 2020 02:03:08

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:34:50



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:56', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:38:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:39:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:39:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:39:06', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered 'None (0)'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:39:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7'	System	13 Aug 2020 17:39:19
User entered 'No (N)'	System	13 Aug 2020 17:39:19

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-13T13:39:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f74853d7-5800-418b-841c-506910a84da7' User entered '13 Aug 2020 13:39'	System	13 Aug 2020 17:39:19
	System	13 Aug 2020 17:39:19



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 13:21'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 15:51'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:26', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'None (0)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered 'No (N)'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-14T08:14:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '460e8ae9-c572-4302-9a7f-5a682361c673' User entered '14 Aug 2020 08:14'	System	14 Aug 2020 12:14:52
	System	14 Aug 2020 12:14:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '13 Aug 2020 16:46'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 2'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:31', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:35', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'None (0)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered 'No (N)'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T00:46:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e84ecada-334c-444c-bf51-c0614acc580c' User entered '15 Aug 2020 00:46'	System	15 Aug 2020 04:46:52
	System	15 Aug 2020 04:46:52

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 3'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:37', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'None (0)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:02:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered 'No (N)'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-15T22:03:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '831016f2-e290-4976-9764-1587ce578ffe' User entered '15 Aug 2020 22:03'	System	16 Aug 2020 02:03:04
	System	16 Aug 2020 02:03:04

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 4'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:01:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:08', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'None (0)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered 'No (N)'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-16T22:02:58', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '67c48d2e-8fe7-451a-9bbf-c3772fbd225a' User entered '16 Aug 2020 22:02'	System	17 Aug 2020 02:03:00
	System	17 Aug 2020 02:03:00

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 5'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:01:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:02:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:02:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'None (0)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:02:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered 'No (N)'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-17T22:02:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdb2c547-ffd8-44d2-9b74-cf4f8eeec3a1' User entered '17 Aug 2020 22:02'	System	18 Aug 2020 02:02:17
	System	18 Aug 2020 02:02:17

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:34:50



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 6'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780' User entered 'None (0)'	System	19 Aug 2020 01:50:33
	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:49:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780' User entered 'None (0)'	System	19 Aug 2020 01:50:33
	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780'	System	19 Aug 2020 01:50:33
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:18', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780'	System	19 Aug 2020 01:50:33
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780' User entered 'None (0)'	System	19 Aug 2020 01:50:33
	System	19 Aug 2020 01:50:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780'	System	19 Aug 2020 01:50:33
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:50:33



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780' User entered 'No (N)'	System	19 Aug 2020 01:50:33
	System	19 Aug 2020 01:50:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-18T21:50:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '58328e5c-3c8b-4f4b-a683-75e56ca22780' User entered '18 Aug 2020 21:50'	System	19 Aug 2020 01:50:33
	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 7'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:03:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94'	System	20 Aug 2020 02:05:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:03:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94' User entered 'None (0)'	System	20 Aug 2020 02:05:59
	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:04:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94'	System	20 Aug 2020 02:05:59
User entered 'Significant; prevents daily activity (3)'	System	20 Aug 2020 02:05:59



US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:04:26', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94' User entered 'None (0)'	System	20 Aug 2020 02:05:59
	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:04:31', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94' User entered 'None (0)'	System	20 Aug 2020 02:05:59
	System	20 Aug 2020 02:05:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:05:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94'	System	20 Aug 2020 02:05:59
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:05:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94'	System	20 Aug 2020 02:05:59
User entered 'No (N)'	System	20 Aug 2020 02:05:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-19T22:05:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8cad34f8-8c7c-4ced-a72a-dc20b89a2c94' User entered '19 Aug 2020 22:05'	System	20 Aug 2020 02:05:59
	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:05:59
User entered 'Day 8'	System	20 Aug 2020 02:05:59



US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:02:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3cdbaf69-69fe-414e-b512-7622e4f9ff2c'	System	21 Aug 2020 02:02:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Aug 2020 02:02:25

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:02:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '3cdbaf69-69fe-414e-b512-7622e4f9ff2c' User entered '20 Aug 2020 22:02'	System	21 Aug 2020 02:02:25
	System	21 Aug 2020 02:02:25

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:05:59
User entered 'Day 9'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f495f00e-a4d6-46dc-aeef-90285b0faed5'	System	22 Aug 2020 02:01:32
User entered 'No interference with activity (1)'	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:01:27', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f495f00e-a4d6-46dc-aeef-90285b0faed5' User entered '21 Aug 2020 22:01'	System	22 Aug 2020 02:01:32
	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 02:05:59



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	21 Aug 2020 02:02:25
User entered 'Day 10'	System	21 Aug 2020 02:02:25

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7d586079-2f1d-477f-888d-319144dea6d7'	System	23 Aug 2020 01:57:15
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:57:15

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7d586079-2f1d-477f-888d-319144dea6d7'	System	23 Aug 2020 01:57:15
User entered '22 Aug 2020 21:57'	System	23 Aug 2020 01:57:15

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:02:25

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:02:25

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	22 Aug 2020 02:01:32
User entered 'Day 11'	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:02:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e8621bce-3eec-4134-b177-772e3e81e781' User entered 'No interference with activity (1)'	System	24 Aug 2020 02:02:38
	System	24 Aug 2020 02:02:38



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:02:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e8621bce-3eec-4134-b177-772e3e81e781' User entered '23 Aug 2020 22:02'	System	24 Aug 2020 02:02:38
	System	24 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:01:32

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	23 Aug 2020 01:57:15
User entered 'Day 12'	System	23 Aug 2020 01:57:15

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '16757fc0-e579-4c84-9121-ba9de8fb0c64' User entered 'No interference with activity (1)'	System	25 Aug 2020 01:29:00
	System	25 Aug 2020 01:29:00

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:28:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '16757fc0-e579-4c84-9121-ba9de8fb0c64' User entered '24 Aug 2020 21:28'	System	25 Aug 2020 01:29:00
	System	25 Aug 2020 01:29:00

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:57:15

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:57:15



US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	24 Aug 2020 02:02:38
User entered 'Day 13'	System	24 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd2ba900a-7ae3-4c5b-8414-d6a18435a0a9' User entered 'No interference with activity (1)'	System	26 Aug 2020 02:01:46
	System	26 Aug 2020 02:01:46

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:01:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd2ba900a-7ae3-4c5b-8414-d6a18435a0a9' User entered '25 Aug 2020 22:01'	System	26 Aug 2020 02:01:46
	System	26 Aug 2020 02:01:46

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 02:02:38

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(13)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	25 Aug 2020 01:29:00
User entered 'Day 14'	System	25 Aug 2020 01:29:00

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:54', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'bf9d4806-20bc-4617-ae09-14eef3da058f' User entered 'No interference with activity (1)'	System	27 Aug 2020 02:02:01
	System	27 Aug 2020 02:02:01

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:01:56', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'bf9d4806-20bc-4617-ae09-14eef3da058f' User entered '26 Aug 2020 22:01'	System	27 Aug 2020 02:02:01
	System	27 Aug 2020 02:02:01



US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:29:00

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:29:00

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	26 Aug 2020 02:01:46
User entered 'Day 15'	System	26 Aug 2020 02:01:46

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:14', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '43792f2a-959e-4cb9-ad8b-20f710bfa33c'	System	28 Aug 2020 01:53:19
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:53:19

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:17', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '43792f2a-959e-4cb9-ad8b-20f710bfa33c' User entered '27 Aug 2020 21:53'	System	28 Aug 2020 01:53:19
	System	28 Aug 2020 01:53:19

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:01:46

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:01:46

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	27 Aug 2020 02:02:01
User entered 'Day 16'	System	27 Aug 2020 02:02:01



US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:42', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '28fe1619-5ccc-410f-a7ed-0eef7bbf24fd' User entered 'None (0)'	System	29 Aug 2020 01:37:49
	System	29 Aug 2020 01:37:49

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '28fe1619-5ccc-410f-a7ed-0eef7bbf24fd' User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:37:49
	System	29 Aug 2020 01:37:49

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:02:01

US3352072

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:02:01

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	19 Aug 2020 01:50:33
User entered 'Day 8'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:02:33', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd6b1ade7-068b-4afd-937e-6ada9067abbd' User entered 'Some interference with activity (2)'	System	21 Aug 2020 02:02:38
	System	21 Aug 2020 02:02:38

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:02:36', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'd6b1ade7-068b-4afd-937e-6ada9067abbd' User entered '20 Aug 2020 22:02'	System	21 Aug 2020 02:02:38
	System	21 Aug 2020 02:02:38

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:50:33



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:05:59
User entered 'Day 9'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '5516ad4b-c059-4b96-811a-3fec7402eb36'	System	22 Aug 2020 02:02:16
User entered 'Some interference with activity (2)'	System	22 Aug 2020 02:02:16

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '5516ad4b-c059-4b96-811a-3fec7402eb36' User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:16
	System	22 Aug 2020 02:02:16

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	21 Aug 2020 02:02:38
User entered 'Day 10'	System	21 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6374b69f-0270-4465-9178-4968df3ca513' User entered 'Some interference with activity (2)'	System	23 Aug 2020 01:57:26
	System	23 Aug 2020 01:57:26



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6374b69f-0270-4465-9178-4968df3ca513' User entered '22 Aug 2020 21:57'	System	23 Aug 2020 01:57:26
	System	23 Aug 2020 01:57:26

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:02:38

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	22 Aug 2020 02:02:16
User entered 'Day 11'	System	22 Aug 2020 02:02:16

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:03:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8760baa3-adc8-4ffb-a672-b88ff90c9c97'	System	24 Aug 2020 02:03:54
User entered 'No interference with activity (1)'	System	24 Aug 2020 02:03:54

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:03:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8760baa3-adc8-4ffb-a672-b88ff90c9c97'	System	24 Aug 2020 02:03:54
User entered '23 Aug 2020 22:03'	System	24 Aug 2020 02:03:54

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:02:16

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:02:16



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	23 Aug 2020 01:57:26
User entered 'Day 12'	System	23 Aug 2020 01:57:26

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:29:07', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ff1c9df6-9cfb-4ff8-87b8-13ed179d2df3'	System	25 Aug 2020 01:29:24
User entered 'Some interference with activity (2)'	System	25 Aug 2020 01:29:24

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:29:20', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ff1c9df6-9cfb-4ff8-87b8-13ed179d2df3'	System	25 Aug 2020 01:29:24
User entered '24 Aug 2020 21:29'	System	25 Aug 2020 01:29:24

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:57:26

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:57:26

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	24 Aug 2020 02:03:54
User entered 'Day 13'	System	24 Aug 2020 02:03:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:02:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b52cda01-6cf5-4c6d-9952-16353502f367'	System	26 Aug 2020 02:02:10
User entered 'Some interference with activity (2)'	System	26 Aug 2020 02:02:10

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:02:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b52cda01-6cf5-4c6d-9952-16353502f367'	System	26 Aug 2020 02:02:10
User entered '25 Aug 2020 22:02'	System	26 Aug 2020 02:02:10



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 02:03:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 02:03:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	25 Aug 2020 01:29:24
User entered 'Day 14'	System	25 Aug 2020 01:29:24

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:02:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '818a0682-9e60-48ac-8206-8292f3262b88'	System	27 Aug 2020 02:02:39
User entered 'Some interference with activity (2)'	System	27 Aug 2020 02:02:39

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:02:37', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '818a0682-9e60-48ac-8206-8292f3262b88' User entered '26 Aug 2020 22:02'	System	27 Aug 2020 02:02:39
	System	27 Aug 2020 02:02:39

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:29:24

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:29:24

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	26 Aug 2020 02:02:10
User entered 'Day 15'	System	26 Aug 2020 02:02:10



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6981cf0-aaf6-4213-bd33-11caeb3dd975'	System	28 Aug 2020 01:53:34
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:53:34

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:30', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b6981cf0-aaf6-4213-bd33-11caeb3dd975' User entered '27 Aug 2020 21:53'	System	28 Aug 2020 01:53:34
	System	28 Aug 2020 01:53:34

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:02:10

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:02:10

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	27 Aug 2020 02:02:39
User entered 'Day 16'	System	27 Aug 2020 02:02:39

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'bf9a4c47-a201-42fd-a373-fd1cefea0672'	System	29 Aug 2020 01:37:54
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:37:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'bf9a4c47-a201-42fd-a373-fd1cefea0672' User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:37:54
	System	29 Aug 2020 01:37:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:02:39



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:02:39

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(17)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	28 Aug 2020 01:53:34
User entered 'Day 17'	System	28 Aug 2020 01:53:34

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(17)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '35f538c2-a5a0-4c30-8235-8ed8904d684c' User entered 'No interference with activity (1)'	System	30 Aug 2020 01:51:44
	System	30 Aug 2020 01:51:44

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '35f538c2-a5a0-4c30-8235-8ed8904d684c' User entered '29 Aug 2020 21:51'	System	30 Aug 2020 01:51:44
	System	30 Aug 2020 01:51:44

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:53:34

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:53:34

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	29 Aug 2020 01:37:54
User entered 'Day 18'	System	29 Aug 2020 01:37:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(18)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:17', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b67a6df6-b5e6-45af-8884-81b65eb0a31b'	System	31 Aug 2020 03:31:25
User entered 'No interference with activity (1)'	System	31 Aug 2020 03:31:25



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:20', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b67a6df6-b5e6-45af-8884-81b65eb0a31b' User entered '30 Aug 2020 23:31'	System	31 Aug 2020 03:31:25
	System	31 Aug 2020 03:31:25

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:37:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:37:54

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(19)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	30 Aug 2020 01:51:44
User entered 'Day 19'	System	30 Aug 2020 01:51:44

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(19)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6c44147a-460e-4df5-a1f5-a53ab3b0db5f' User entered 'No interference with activity (1)'	System	01 Sep 2020 02:00:52
	System	01 Sep 2020 02:00:52

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '6c44147a-460e-4df5-a1f5-a53ab3b0db5f' User entered '31 Aug 2020 22:00'	System	01 Sep 2020 02:00:52
	System	01 Sep 2020 02:00:52

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 01:51:44

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 01:51:44



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(20)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	31 Aug 2020 03:31:25
User entered 'Day 20'	System	31 Aug 2020 03:31:25

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(20)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:12', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c58f0749-6491-4921-8395-34d33a074039'	System	02 Sep 2020 02:01:17
User entered 'No interference with activity (1)'	System	02 Sep 2020 02:01:17

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(20)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c58f0749-6491-4921-8395-34d33a074039' User entered '01 Sep 2020 22:01'	System	02 Sep 2020 02:01:17
	System	02 Sep 2020 02:01:17

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:25

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:25

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(21)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	01 Sep 2020 02:00:52
User entered 'Day 21'	System	01 Sep 2020 02:00:52

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(21)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7cab4e48-5a63-40ea-ada0-b7834f8887ee' User entered 'No interference with activity (1)'	System	03 Sep 2020 01:45:43
	System	03 Sep 2020 01:45:43

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7cab4e48-5a63-40ea-ada0-b7834f8887ee' User entered '02 Sep 2020 21:45'	System	03 Sep 2020 01:45:43
	System	03 Sep 2020 01:45:43



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 02:00:52

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 02:00:52

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(22)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	02 Sep 2020 02:01:17
User entered 'Day 22'	System	02 Sep 2020 02:01:17

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(22)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b271e70c-3686-4377-9e6a-a19bb0395da2'	System	04 Sep 2020 01:45:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 01:45:55

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(22)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b271e70c-3686-4377-9e6a-a19bb0395da2'	System	04 Sep 2020 01:45:55
User entered '03 Sep 2020 21:45'	System	04 Sep 2020 01:45:55

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:01:17

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:01:17

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(23)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	03 Sep 2020 01:45:43
User entered 'Day 23'	System	03 Sep 2020 01:45:43



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(23)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:52', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8ab3e566-d787-4357-bf04-21060a77d5fb' User entered 'No interference with activity (1)'	System	05 Sep 2020 02:00:58
	System	05 Sep 2020 02:00:58

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(23)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:00:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8ab3e566-d787-4357-bf04-21060a77d5fb' User entered '04 Sep 2020 22:00'	System	05 Sep 2020 02:00:58
	System	05 Sep 2020 02:00:58

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:45:43

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:45:43

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	04 Sep 2020 01:45:55
User entered 'Day 24'	System	04 Sep 2020 01:45:55

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(24)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:41', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '03241159-51b7-46b1-b439-abd1c657ac31'	System	06 Sep 2020 00:44:45
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:44:45

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(24)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '03241159-51b7-46b1-b439-abd1c657ac31' User entered '05 Sep 2020 20:44'	System	06 Sep 2020 00:44:45
	System	06 Sep 2020 00:44:45

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:45:55



US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:45:55

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(25)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	05 Sep 2020 02:00:58
User entered 'Day 25'	System	05 Sep 2020 02:00:58

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(25)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:15', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ae4ac9a9-3b75-4f26-83e3-0cc220bdcca3'	System	07 Sep 2020 01:47:19
User entered 'No interference with activity (1)'	System	07 Sep 2020 01:47:19

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:17', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ae4ac9a9-3b75-4f26-83e3-0cc220bdcca3' User entered '06 Sep 2020 21:47'	System	07 Sep 2020 01:47:19
	System	07 Sep 2020 01:47:19

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(25)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 02:00:58

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 02:00:58

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(26)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	06 Sep 2020 00:44:45
User entered 'Day 26'	System	06 Sep 2020 00:44:45

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(26)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '72e3e947-215d-46de-bf61-0cce11353a7d' User entered 'None (0)'	System	08 Sep 2020 10:35:16
	System	08 Sep 2020 10:35:16



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(26)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:12', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '72e3e947-215d-46de-bf61-0cce11353a7d' User entered '08 Sep 2020 06:35'	System	08 Sep 2020 10:35:16
	System	08 Sep 2020 10:35:16

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 00:44:45

US3352072

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 00:44:45

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	19 Aug 2020 01:50:33
User entered 'Day 8'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:03:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'cddac8b8-26d7-40e3-8b43-2e5f3bfa767d'	System	21 Aug 2020 02:03:07
User entered 'Some interference with activity not requiring medical attention (2)'	System	21 Aug 2020 02:03:07

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:50:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:50:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:03:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'cddac8b8-26d7-40e3-8b43-2e5f3bfa767d' User entered '20 Aug 2020 22:03'	System	21 Aug 2020 02:03:07
	System	21 Aug 2020 02:03:07



US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:05:59
User entered 'Day 9'	System	20 Aug 2020 02:05:59

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1b08438e-996d-43f3-9c60-997df00928'	System	22 Aug 2020 02:02:26
User entered 'No interference with activity (1)'	System	22 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 02:05:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(9)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 02:05:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(9)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1b08438e-996d-43f3-9c60-997df00928'	System	22 Aug 2020 02:02:26
User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:26

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	21 Aug 2020 02:03:07
User entered 'Day 10'	System	21 Aug 2020 02:03:07

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b4f881cb-ff79-4c82-9467-38ee269fee36' User entered 'None (0)'	System	23 Aug 2020 01:57:37
	System	23 Aug 2020 01:57:37

US3352072

Folder: Diary Dose 1 (1)

Form: Chills\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:03:07



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(10)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:03:07

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Chills\_Day(10)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:35', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b4f881cb-ff79-4c82-9467-38ee269fee36' User entered '22 Aug 2020 21:57'	System	23 Aug 2020 01:57:37
	System	23 Aug 2020 01:57:37

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	19 Aug 2020 01:50:33
User entered 'Day 8'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:03:12', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fafa84d3-7f8d-4231-a073-1aa026a56079' User entered 'No (N)'	System	21 Aug 2020 02:03:17
	System	21 Aug 2020 02:03:17

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-20T22:03:14', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fafa84d3-7f8d-4231-a073-1aa026a56079' User entered '20 Aug 2020 22:03'	System	21 Aug 2020 02:03:17
	System	21 Aug 2020 02:03:17

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:50:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:50:33

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	20 Aug 2020 02:02:11
User entered 'Day 9'	System	20 Aug 2020 02:02:11



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00ebd5b8-a171-4c4b-81d0-1b926f75b6af' User entered 'Yes (Y)'	System	22 Aug 2020 02:02:42
	System	22 Aug 2020 02:02:42

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-21T22:02:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '00ebd5b8-a171-4c4b-81d0-1b926f75b6af' User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:42
	System	22 Aug 2020 02:02:42

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 02:02:11

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	21 Aug 2020 02:01:56
User entered 'Day 10'	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '57fb26f4-1b99-4099-972b-0ad6c04725ff'	System	23 Aug 2020 01:57:54
User entered 'Yes (Y)'	System	23 Aug 2020 01:57:54

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-22T21:57:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '57fb26f4-1b99-4099-972b-0ad6c04725ff' User entered '22 Aug 2020 21:57'	System	23 Aug 2020 01:57:54
	System	23 Aug 2020 01:57:54

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:01:56



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:01:56

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	22 Aug 2020 02:01:32
User entered 'Day 11'	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'df200b38-6d43-491c-914b-057545d76030'	System	24 Aug 2020 02:04:08
User entered 'Yes (Y)'	System	24 Aug 2020 02:04:08

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-23T22:04:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'df200b38-6d43-491c-914b-057545d76030'	System	24 Aug 2020 02:04:08
User entered '23 Aug 2020 22:04'	System	24 Aug 2020 02:04:08

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 02:01:32

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 02:01:32

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	23 Aug 2020 01:57:02
User entered 'Day 12'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:29:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c066a859-9583-4667-bacf-8a28ecf3e4fb' User entered 'Yes (Y)'	System	25 Aug 2020 01:29:35
	System	25 Aug 2020 01:29:35



**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-24T21:29:33', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c066a859-9583-4667-bacf-8a28ecf3e4fb' User entered '24 Aug 2020 21:29'	System	25 Aug 2020 01:29:35
	System	25 Aug 2020 01:29:35

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:57:02

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:57:02

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	24 Aug 2020 02:01:58
User entered 'Day 13'	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:02:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '99ecc546-6489-4026-b390-90d2c5f3a455'	System	26 Aug 2020 02:02:31
User entered 'Yes (Y)'	System	26 Aug 2020 02:02:31

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-25T22:02:26', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '99ecc546-6489-4026-b390-90d2c5f3a455'	System	26 Aug 2020 02:02:31
User entered '25 Aug 2020 22:02'	System	26 Aug 2020 02:02:31

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 02:01:58

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 02:01:58



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	25 Aug 2020 01:28:47
User entered 'Day 14'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:02:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdd5a80d-d0ed-45b4-9a9c-a5bca87d3acf' User entered 'Yes (Y)'	System	27 Aug 2020 02:02:48
	System	27 Aug 2020 02:02:48

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-26T22:02:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fdd5a80d-d0ed-45b4-9a9c-a5bca87d3acf' User entered '26 Aug 2020 22:02'	System	27 Aug 2020 02:02:48
	System	27 Aug 2020 02:02:48

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:28:47

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	26 Aug 2020 02:01:25
User entered 'Day 15'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:34', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ece13799-97d1-4b18-bbc5-352e59581633'	System	28 Aug 2020 01:53:38
User entered 'Yes (Y)'	System	28 Aug 2020 01:53:38

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-27T21:53:36', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'ece13799-97d1-4b18-bbc5-352e59581633'	System	28 Aug 2020 01:53:38
User entered '27 Aug 2020 21:53'	System	28 Aug 2020 01:53:38



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 02:01:25

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	27 Aug 2020 02:01:43
User entered 'Day 16'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7a5b2aeb-8392-4ed6-88c6-c9f86d2e4abf' User entered 'Yes (Y)'	System	29 Aug 2020 01:38:01
	System	29 Aug 2020 01:38:01

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-28T21:37:58', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7a5b2aeb-8392-4ed6-88c6-c9f86d2e4abf' User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:38:01
	System	29 Aug 2020 01:38:01

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:01:43

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	28 Aug 2020 01:53:12
User entered 'Day 17'	System	28 Aug 2020 01:53:12



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b22d48ad-6ece-4824-8fea-6a9beb15e1b4' User entered 'Yes (Y)'	System	30 Aug 2020 01:51:51
	System	30 Aug 2020 01:51:51

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-29T21:51:48', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'b22d48ad-6ece-4824-8fea-6a9beb15e1b4'	System	30 Aug 2020 01:51:51
User entered '29 Aug 2020 21:51'	System	30 Aug 2020 01:51:51

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:53:12

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:53:12

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	29 Aug 2020 01:37:37
User entered 'Day 18'	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:29', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '795f52c4-6b38-4f3e-938f-9aea1e4c2c67'	System	31 Aug 2020 03:31:33
User entered 'Yes (Y)'	System	31 Aug 2020 03:31:33

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-30T23:31:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '795f52c4-6b38-4f3e-938f-9aea1e4c2c67' User entered '30 Aug 2020 23:31'	System	31 Aug 2020 03:31:33
	System	31 Aug 2020 03:31:33

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 01:37:37



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 01:37:37

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	30 Aug 2020 01:51:31
User entered 'Day 19'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:53', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c76017c7-9fc6-42a6-95d3-26cee3011f02'	System	01 Sep 2020 02:00:59
User entered 'Yes (Y)'	System	01 Sep 2020 02:00:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-08-31T22:00:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c76017c7-9fc6-42a6-95d3-26cee3011f02'	System	01 Sep 2020 02:00:59
User entered '31 Aug 2020 22:00'	System	01 Sep 2020 02:00:59

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 01:51:31

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 01:51:31

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	31 Aug 2020 03:31:14
User entered 'Day 20'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e08c8f19-fa40-4131-8ebe-031f1c038fe7'	System	02 Sep 2020 02:01:25
User entered 'Yes (Y)'	System	02 Sep 2020 02:01:25



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-01T22:01:22', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e08c8f19-fa40-4131-8ebe-031f1c038fe7' User entered '01 Sep 2020 22:01'	System	02 Sep 2020 02:01:25
	System	02 Sep 2020 02:01:25

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 03:31:14

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	01 Sep 2020 02:00:47
User entered 'Day 21'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c9ba7d6c-c6ba-44fa-96f2-50d84d69790b' User entered 'Yes (Y)'	System	03 Sep 2020 01:45:51
	System	03 Sep 2020 01:45:51

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-02T21:45:47', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c9ba7d6c-c6ba-44fa-96f2-50d84d69790b' User entered '02 Sep 2020 21:45'	System	03 Sep 2020 01:45:51
	System	03 Sep 2020 01:45:51

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 02:00:47

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 02:00:47



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	02 Sep 2020 02:01:09
User entered 'Day 22'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:56', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f1184709-c1dd-4a21-931d-92d8e3e1ebbe' User entered 'Yes (Y)'	System	04 Sep 2020 01:45:59
	System	04 Sep 2020 01:45:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-03T21:45:57', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f1184709-c1dd-4a21-931d-92d8e3e1ebbe' User entered '03 Sep 2020 21:45'	System	04 Sep 2020 01:45:59
	System	04 Sep 2020 01:45:59

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(22)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 02:01:09

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	03 Sep 2020 01:45:36
User entered 'Day 23'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:01:05', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e2a4ce56-3d85-4ee4-b253-f2982dc124f0' User entered 'Yes (Y)'	System	05 Sep 2020 02:01:14
	System	05 Sep 2020 02:01:14

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-04T22:01:08', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e2a4ce56-3d85-4ee4-b253-f2982dc124f0' User entered '04 Sep 2020 22:01'	System	05 Sep 2020 02:01:14
	System	05 Sep 2020 02:01:14



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(23)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:45:36

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	04 Sep 2020 01:45:45
User entered 'Day 24'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7287a3d3-a5b7-476b-bdce-84ffc8abe80b' User entered 'Yes (Y)'	System	06 Sep 2020 00:44:58
	System	06 Sep 2020 00:44:58

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-05T20:44:56', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7287a3d3-a5b7-476b-bdce-84ffc8abe80b' User entered '05 Sep 2020 20:44'	System	06 Sep 2020 00:44:58
	System	06 Sep 2020 00:44:58

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(24)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:45:45

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	05 Sep 2020 02:00:51
User entered 'Day 25'	System	05 Sep 2020 02:00:51



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:21', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '030939d0-f5be-43f9-849a-b2c043e7b581' User entered 'Yes (Y)'	System	07 Sep 2020 01:47:26
	System	07 Sep 2020 01:47:26

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(25)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-06T21:47:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '030939d0-f5be-43f9-849a-b2c043e7b581' User entered '06 Sep 2020 21:47'	System	07 Sep 2020 01:47:26
	System	07 Sep 2020 01:47:26

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 02:00:51

**US3352072**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 11 Aug 2021 22:38:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 02:00:51

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	06 Sep 2020 00:44:30
User entered 'Day 26'	System	06 Sep 2020 00:44:30

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '47d731c8-6147-41a6-938b-ce316b523082'	System	08 Sep 2020 10:35:20
User entered 'Yes (Y)'	System	08 Sep 2020 10:35:20

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-09-08T06:35:18', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '47d731c8-6147-41a6-938b-ce316b523082' User entered '08 Sep 2020 06:35'	System	08 Sep 2020 10:35:20
	System	08 Sep 2020 10:35:20

US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 00:44:30



US3352072

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(26)

Generated On: 11 Aug 2021 22:38:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 00:44:30

US3352072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:30:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:17:09

US3352072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:30:59
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 19:17:09

US3352072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:30:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Aug 2020 19:17:09

US3352072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:30:59
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:17:09

US3352072

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:31:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:17:16

US3352072

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User entered 'I'	System	20 Aug 2020 19:17:16

US3352072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Sep 2020 15:22:28
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Sep 2020 15:21:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:21:55



US3352072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:21:55

US3352072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:22:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	25 Sep 2020 15:21:55

US3352072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:22:28
User entered 'CONVALESCENT PERIOD'	(b) (4), (b) (6)	25 Sep 2020 15:21:55

US3352072

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:22:32

US3352072

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:27
User entered 'I'	System	25 Sep 2020 15:22:32

US3352072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:22:38

US3352072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:22:38

US3352072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:22:38



US3352072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:22:38

US3352072

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:22:41

US3352072

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User entered 'I'	System	25 Sep 2020 15:22:41

US3352072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Per CDM -Kindly consider to update appropriate data on exposure form.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:44:36
Query 'Per CDM -Kindly consider to update appropriate data on exposure form.' answered with 'subject was positive for covid 19. illness visit and tele medicine visit were done into subject recovered ' (Site from DM).	Matthew Muniz (b) (4)	28 Oct 2020 15:05:09
User opened query 'Per CDM -Kindly consider to update appropriate data on exposure form.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:25:09
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:22:53

US3352072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:22:53

US3352072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:22:53

US3352072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered 'VISIT2'	System	25 Sep 2020 15:22:53

US3352072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:23:04



US3352072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:23
User entered '1'	System	25 Sep 2020 15:23:04

US3352072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:23:27

US3352072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:23:27

US3352072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:23:27

US3352072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:23:27

US3352072

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:23:30

US3352072

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'I'	System	25 Sep 2020 15:23:30

US3352072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:04:52



US3352072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:04:52

US3352072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 16:04:52

US3352072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:52

US3352072

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:04:55

US3352072

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'I'	System	25 Sep 2020 16:04:55

**US3352072**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	01 Oct 2020 13:24:18

US3352072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '1 Oct 2020'	Yulexis Amestoy (b) (4)	01 Oct 2020 13:24:18

US3352072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	01 Oct 2020 13:24:18



US3352072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	Yulexis Amestoy (b) (4)	01 Oct 2020 13:24:18

US3352072

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	01 Oct 2020 13:24:22

**US3352072**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'I'	System	01 Oct 2020 13:24:22

US3352072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:12:36
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	06 Oct 2020 14:36:28

US3352072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:19
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:26:40
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:40:09
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 20:40:04
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:40:04
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:12:36
User entered '6 Oct 2020'	Matthew Muniz (b) (4)	06 Oct 2020 14:36:28

US3352072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:12:36
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	06 Oct 2020 14:36:28

US3352072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'VISIT3'	System	06 Oct 2020 14:36:28

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23



US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you! ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:11:42
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you! ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	06 Nov 2020 15:09:38
DataPoint Un-verified.	Matthew Muniz (b) (4)	06 Nov 2020 15:09:34
User entered '06 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 15:09:34
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you! ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:26:55
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '6 Oct 2020'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '06:45'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered '06 Oct 2020 06:45'	System	06 Nov 2020 15:09:34
User entered '6 Oct 2020 06:45'	System	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '36.7' C	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered empty.	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '63'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'bpm'	System	06 Oct 2020 14:37:23



US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '13'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'breaths/min'	System	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '120'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'mmHg'	System	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:04
User entered '76'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'mmHg'	System	06 Oct 2020 14:37:23

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:08:04

US3352072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:08:04



US3352072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:54
User entered 'No (N)'	Matthew Muniz (b) (4)	06 Oct 2020 14:37:31

US3352072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:13:54
User entered empty.	Matthew Muniz (b) (4)	06 Oct 2020 14:37:31

US3352072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:14:11
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	06 Oct 2020 14:38:01

US3352072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Un-verified.	Matthew Muniz (b) (4)	06 Nov 2020 15:09:26
User entered '06 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 15:09:26
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:14:11
User entered '6 Oct 2020'	Matthew Muniz (b) (4)	06 Oct 2020 14:38:01

US3352072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:14:11
User entered '08:56'	Matthew Muniz (b) (4)	06 Oct 2020 14:38:01

US3352072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered '06 Oct 2020 08:56'	System	06 Nov 2020 15:09:26
User entered '6 Oct 2020 08:56'	System	06 Oct 2020 14:38:01

US3352072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:14:17
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	06 Oct 2020 14:38:11

US3352072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:04
User entered 'I'	System	06 Oct 2020 14:38:11



US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 64'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-13T14:17:58', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fa4c3df6-1f49-4440-b355-ce2b851ba18c' User entered 'No (N)'	System	13 Oct 2020 18:18:19
	System	13 Oct 2020 18:18:19

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-13T14:18:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fa4c3df6-1f49-4440-b355-ce2b851ba18c'	System	13 Oct 2020 18:18:19
User entered 'No (N)'	System	13 Oct 2020 18:18:19

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-13T14:18:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'fa4c3df6-1f49-4440-b355-ce2b851ba18c' User entered '13 Oct 2020 14:18:16'	System	13 Oct 2020 18:18:19
	System	13 Oct 2020 18:18:19

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 71'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-20T21:19:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a0d87b5-84e4-459e-9105-3609469b9911'	System	21 Oct 2020 01:20:07
User entered 'No (N)'	System	21 Oct 2020 01:20:07



US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-20T21:19:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a0d87b5-84e4-459e-9105-3609469b9911'	System	21 Oct 2020 01:20:07
User entered 'No (N)'	System	21 Oct 2020 01:20:07

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-20T21:20:01', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a0d87b5-84e4-459e-9105-3609469b9911' User entered '20 Oct 2020 21:20:01'	System	21 Oct 2020 01:20:07
	System	21 Oct 2020 01:20:07

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 78'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-27T12:23:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f9a6050a-855b-4f83-8b35-1c417b59b2c9' User entered 'No (N)'	System	27 Oct 2020 16:23:27
	System	27 Oct 2020 16:23:27

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-27T12:23:03', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f9a6050a-855b-4f83-8b35-1c417b59b2c9'	System	27 Oct 2020 16:23:27
User entered 'No (N)'	System	27 Oct 2020 16:23:27

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-10-27T12:23:23', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'f9a6050a-855b-4f83-8b35-1c417b59b2c9' User entered '27 Oct 2020 12:23:23'	System	27 Oct 2020 16:23:27
	System	27 Oct 2020 16:23:27



US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 92'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-11T10:09:51', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7b511043-534c-44e4-aecf-2d1f69d699d7'	System	11 Nov 2020 15:10:02
User entered 'No (N)'	System	11 Nov 2020 15:10:02

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-11T10:09:55', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7b511043-534c-44e4-aecf-2d1f69d699d7'	System	11 Nov 2020 15:10:02
User entered 'No (N)'	System	11 Nov 2020 15:10:02

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-11T10:09:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7b511043-534c-44e4-aecf-2d1f69d699d7' User entered '11 Nov 2020 10:09:59'	System	11 Nov 2020 15:10:02
	System	11 Nov 2020 15:10:02

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:34:50



**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03
Data entry locked.	System	13 Aug 2020 17:34:50
User entered 'Day 99'	System	13 Aug 2020 17:34:50

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

US3352072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:11:03
Data entry locked.	System	13 Aug 2020 17:34:50
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:34:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-21T13:18:14', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34021bce-4f7e-4a70-829f-018cf3ceb0ea' User entered 'No (N)'	System	21 Nov 2020 18:18:22
	System	21 Nov 2020 18:18:22

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-21T13:18:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34021bce-4f7e-4a70-829f-018cf3ceb0ea' User entered 'No (N)'	System	21 Nov 2020 18:18:22

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-21T13:18:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34021bce-4f7e-4a70-829f-018cf3ceb0ea' User entered '21 Nov 2020 13:18:19'	System	21 Nov 2020 18:18:22
	System	21 Nov 2020 18:18:22



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-30T12:00:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '015881dd-8d77-44f4-a00c-a1cd180f4e91' User entered 'No (N)'	System	30 Nov 2020 17:00:46
	System	30 Nov 2020 17:00:46

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-30T12:00:32', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '015881dd-8d77-44f4-a00c-a1cd180f4e91'	System	30 Nov 2020 17:00:46
User entered 'No (N)'	System	30 Nov 2020 17:00:46

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C89220B-94B5-40BD-B3F5-6E6634877ECD)', Time: '2020-11-30T12:00:36', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '015881dd-8d77-44f4-a00c-a1cd180f4e91' User entered '30 Nov 2020 12:00:36'	System	30 Nov 2020 17:00:46
	System	30 Nov 2020 17:00:46

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-09T09:41:16', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d01d48a-78d2-4dcd-a4eb-1d8580fc639e' User entered 'No (N)'	System	09 Dec 2020 14:41:26
	System	09 Dec 2020 14:41:26

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-09T09:41:19', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d01d48a-78d2-4dcd-a4eb-1d8580fc639e' User entered 'No (N)'	System	09 Dec 2020 14:41:26
	System	09 Dec 2020 14:41:26

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-09T09:41:24', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d01d48a-78d2-4dcd-a4eb-1d8580fc639e' User entered '09 Dec 2020 09:41:24'	System	09 Dec 2020 14:41:26
	System	09 Dec 2020 14:41:26

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-12T06:32:25', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '863d8d18-9684-40d0-a76d-d3470ad99c90'	System	12 Dec 2020 11:32:35
User entered 'No (N)'	System	12 Dec 2020 11:32:35



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-12T06:32:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '863d8d18-9684-40d0-a76d-d3470ad99c90'	System	12 Dec 2020 11:32:35
User entered 'No (N)'	System	12 Dec 2020 11:32:35

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-12T06:32:31', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '863d8d18-9684-40d0-a76d-d3470ad99c90'	System	12 Dec 2020 11:32:35
User entered '12 Dec 2020 06:32:31'	System	12 Dec 2020 11:32:35

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-19T10:05:33', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20c498d2-6027-407c-8900-e5e5c64de26e' User entered 'No (N)'	System	19 Dec 2020 15:05:41
	System	19 Dec 2020 15:05:41

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-19T10:05:35', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20c498d2-6027-407c-8900-e5e5c64de26e' User entered 'No (N)'	System	19 Dec 2020 15:05:41
	System	19 Dec 2020 15:05:41

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-19T10:05:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '20c498d2-6027-407c-8900-e5e5c64de26e' User entered '19 Dec 2020 10:05:38'	System	19 Dec 2020 15:05:41
	System	19 Dec 2020 15:05:41



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-28T11:27:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '4b5345ff-bb39-4cc3-ae6a-3f4824d3073b' User entered 'No (N)'	System	28 Dec 2020 17:28:15
	System	28 Dec 2020 17:28:15

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-28T11:28:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '4b5345ff-bb39-4cc3-ae6a-3f4824d3073b'	System	28 Dec 2020 17:28:15
User entered 'No (N)'	System	28 Dec 2020 17:28:15

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2020-12-28T11:28:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '4b5345ff-bb39-4cc3-ae6a-3f4824d3073b' User entered '28 Dec 2020 11:28:13'	System	28 Dec 2020 17:28:15
	System	28 Dec 2020 17:28:15

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-05T09:17:39', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d379ee6-c247-4801-903b-00064541f52d' User entered 'No (N)'	System	05 Jan 2021 14:17:50
	System	05 Jan 2021 14:17:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-05T09:17:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d379ee6-c247-4801-903b-00064541f52d' User entered 'No (N)'	System	05 Jan 2021 14:17:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-05T09:17:49', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9d379ee6-c247-4801-903b-00064541f52d' User entered '05 Jan 2021 09:17:49'	System	05 Jan 2021 14:17:50
	System	05 Jan 2021 14:17:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-10T16:35:59', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2890b8b4-f761-4422-8618-2bc4131746d7'	System	10 Jan 2021 21:36:16
User entered 'No (N)'	System	10 Jan 2021 21:36:16



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-10T16:36:08', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2890b8b4-f761-4422-8618-2bc4131746d7'	System	10 Jan 2021 21:36:16
User entered 'No (N)'	System	10 Jan 2021 21:36:16

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-10T16:36:11', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '2890b8b4-f761-4422-8618-2bc4131746d7' User entered '10 Jan 2021 16:36:11'	System	10 Jan 2021 21:36:16

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-16T21:39:38', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34abe55c-8706-4601-9865-2d632f98cf6f' User entered 'No (N)'	System	17 Jan 2021 02:39:50
	System	17 Jan 2021 02:39:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-16T21:39:40', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34abe55c-8706-4601-9865-2d632f98cf6f' User entered 'No (N)'	System	17 Jan 2021 02:39:50
	System	17 Jan 2021 02:39:50

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-16T21:39:46', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '34abe55c-8706-4601-9865-2d632f98cf6f' User entered '16 Jan 2021 21:39:46'	System	17 Jan 2021 02:39:50
	System	17 Jan 2021 02:39:50



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-24T08:35:44', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a5ad2c42-7f02-49ae-955b-85fdbbc58ac54'	System	24 Jan 2021 13:35:55
User entered 'No (N)'	System	24 Jan 2021 13:35:55

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-24T08:35:47', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a5ad2c42-7f02-49ae-955b-85fdb58ac54'	System	24 Jan 2021 13:35:55
User entered 'No (N)'	System	24 Jan 2021 13:35:55

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-24T08:35:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a5ad2c42-7f02-49ae-955b-85fdb58ac54'	System	24 Jan 2021 13:35:55
User entered '24 Jan 2021 08:35:50'	System	24 Jan 2021 13:35:55

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-31T21:09:02', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '99e6406a-979c-4852-a485-bb5880210608' User entered 'No (N)'	System	01 Feb 2021 02:10:47
	System	01 Feb 2021 02:10:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-31T21:09:04', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '99e6406a-979c-4852-a485-bb5880210608' User entered 'No (N)'	System	01 Feb 2021 02:10:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-01-31T21:09:09', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '99e6406a-979c-4852-a485-bb5880210608' User entered '31 Jan 2021 21:09:09'	System	01 Feb 2021 02:10:47
	System	01 Feb 2021 02:10:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-08T08:14:45', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '72ee1876-50f8-448e-8f6d-405ad1c4267c' User entered 'No (N)'	System	08 Feb 2021 13:14:54
	System	08 Feb 2021 13:14:54



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-08T08:14:47', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '72ee1876-50f8-448e-8f6d-405ad1c4267c' User entered 'No (N)'	System	08 Feb 2021 13:14:54

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-08T08:14:50', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '72ee1876-50f8-448e-8f6d-405ad1c4267c' User entered '08 Feb 2021 08:14:50'	System	08 Feb 2021 13:14:54
	System	08 Feb 2021 13:14:54

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-15T12:00:26', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8c1e9b5f-bda3-4e55-a363-ed971c1f51c1' User entered 'No (N)'	System	15 Feb 2021 17:02:19
	System	15 Feb 2021 17:02:19

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-15T12:00:28', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8c1e9b5f-bda3-4e55-a363-ed971c1f51c1'	System	15 Feb 2021 17:02:19
User entered 'No (N)'	System	15 Feb 2021 17:02:19

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-15T12:00:31', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '8c1e9b5f-bda3-4e55-a363-ed971c1f51c1' User entered '15 Feb 2021 12:00:31'	System	15 Feb 2021 17:02:19
	System	15 Feb 2021 17:02:19



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-20T06:51:09', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9e0fad61-a7f3-4b90-9c25-b4a7081098ec' User entered 'No (N)'	System	20 Feb 2021 11:51:18
	System	20 Feb 2021 11:51:18

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-20T06:51:10', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9e0fad61-a7f3-4b90-9c25-b4a7081098ec'	System	20 Feb 2021 11:51:18
User entered 'No (N)'	System	20 Feb 2021 11:51:18

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-20T06:51:13', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '9e0fad61-a7f3-4b90-9c25-b4a7081098ec' User entered '20 Feb 2021 06:51:13'	System	20 Feb 2021 11:51:18
	System	20 Feb 2021 11:51:18

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-27T00:08:19-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '591a961b-b54f-43d7-8b74-182bb768a024'	System	27 Feb 2021 05:09:37
User entered 'No (N)'	System	27 Feb 2021 05:09:37

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-27T00:08:22-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '591a961b-b54f-43d7-8b74-182bb768a024'	System	27 Feb 2021 05:09:37
User entered 'No (N)'	System	27 Feb 2021 05:09:37

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-02-27T00:08:25-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '591a961b-b54f-43d7-8b74-182bb768a024'	System	27 Feb 2021 05:09:37
User entered '27 Feb 2021 05:08:25'	System	27 Feb 2021 05:09:37

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:11:03

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-08T23:44:36-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e3d7f672-fbb4-4c5c-9179-3f83d7c7c99c'	System	09 Mar 2021 04:44:48
User entered 'No (N)'	System	09 Mar 2021 04:44:48



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-08T23:44:40-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e3d7f672-fbb4-4c5c-9179-3f83d7c7c99c'	System	09 Mar 2021 04:44:48
User entered 'No (N)'	System	09 Mar 2021 04:44:48

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-08T23:44:45-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'e3d7f672-fbb4-4c5c-9179-3f83d7c7c99c'	System	09 Mar 2021 04:44:48
User entered '08 Mar 2021 23:44:45'	System	09 Mar 2021 04:44:48

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-13T10:08:07-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'de42a0be-4154-4527-8b57-d7f33a1e80d0'	System	13 Mar 2021 15:08:16
User entered 'No (N)'	System	13 Mar 2021 15:08:16

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-13T10:08:09-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'de42a0be-4154-4527-8b57-d7f33a1e80d0'	System	13 Mar 2021 15:08:16
User entered 'No (N)'	System	13 Mar 2021 15:08:16

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-13T10:08:12-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'de42a0be-4154-4527-8b57-d7f33a1e80d0' User entered '13 Mar 2021 10:08:12'	System	13 Mar 2021 15:08:16
	System	13 Mar 2021 15:08:16



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-20T01:05:31-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '77ce3cfc-221e-4d39-8015-eca3b444b8c9'	System	20 Mar 2021 05:05:47
User entered 'No (N)'	System	20 Mar 2021 05:05:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-20T01:05:36-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '77ce3cfc-221e-4d39-8015-eca3b444b8c9'	System	20 Mar 2021 05:05:47
User entered 'No (N)'	System	20 Mar 2021 05:05:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-20T01:05:43-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '77ce3cfc-221e-4d39-8015-eca3b444b8c9' User entered '20 Mar 2021 01:05:43'	System	20 Mar 2021 05:05:47
	System	20 Mar 2021 05:05:47

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-27T08:36:57-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a05e18d-d7d4-4161-9ed1-e6c8461cedad' User entered 'No (N)'	System	27 Mar 2021 12:37:05
	System	27 Mar 2021 12:37:05

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-27T08:36:59-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a05e18d-d7d4-4161-9ed1-e6c8461cedad' User entered 'No (N)'	System	27 Mar 2021 12:37:05

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-27T08:37:02-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '1a05e18d-d7d4-4161-9ed1-e6c8461cedad' User entered '27 Mar 2021 08:37:02'	System	27 Mar 2021 12:37:05
	System	27 Mar 2021 12:37:05

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-04T16:30:08-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7c95cf32-0a2c-4594-a4de-2b8c29ef99d3'	System	04 Apr 2021 20:30:19
User entered 'No (N)'	System	04 Apr 2021 20:30:19



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-04T16:30:11-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7c95cf32-0a2c-4594-a4de-2b8c29ef99d3'	System	04 Apr 2021 20:30:19
User entered 'No (N)'	System	04 Apr 2021 20:30:19

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-04T16:30:14-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '7c95cf32-0a2c-4594-a4de-2b8c29ef99d3'	System	04 Apr 2021 20:30:19
User entered '04 Apr 2021 16:30:14'	System	04 Apr 2021 20:30:19

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-10T01:13:42-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '19a785b7-d742-4e42-b3d5-e25f72909e93'	System	13 Apr 2021 22:09:49
User entered 'No (N)'	System	13 Apr 2021 22:09:49

US3352072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-10T01:13:44-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '19a785b7-d742-4e42-b3d5-e25f72909e93'	System	13 Apr 2021 22:09:49
User entered 'No (N)'	System	13 Apr 2021 22:09:49

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-10T01:13:47-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '19a785b7-d742-4e42-b3d5-e25f72909e93'	System	13 Apr 2021 22:09:49
User entered '10 Apr 2021 01:13:47'	System	13 Apr 2021 22:09:49



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-17T00:59:04-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'aeced0ec-3d18-4362-8b78-71d320bcf133'	System	17 Apr 2021 04:59:12
User entered 'No (N)'	System	17 Apr 2021 04:59:12

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-17T00:59:06-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'aeced0ec-3d18-4362-8b78-71d320bcf133'	System	17 Apr 2021 04:59:12
User entered 'No (N)'	System	17 Apr 2021 04:59:12

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-17T00:59:08-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'aeced0ec-3d18-4362-8b78-71d320bcf133'	System	17 Apr 2021 04:59:12
User entered '17 Apr 2021 00:59:08'	System	17 Apr 2021 04:59:12

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-24T17:41:03-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '045d46fb-f4c2-4d10-90fb-7a92c680fc4a' User entered 'No (N)'	System	24 Apr 2021 21:41:11

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-24T17:41:05-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '045d46fb-f4c2-4d10-90fb-7a92c680fc4a'	System	24 Apr 2021 21:41:11
User entered 'No (N)'	System	24 Apr 2021 21:41:11

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-04-24T17:41:07-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: '045d46fb-f4c2-4d10-90fb-7a92c680fc4a' User entered '24 Apr 2021 17:41:07'	System	24 Apr 2021 21:41:11
	System	24 Apr 2021 21:41:11

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-05-02T18:41:09-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c3003591-2231-4850-821b-58e00d9effea'	System	02 May 2021 22:41:18
User entered 'No (N)'	System	02 May 2021 22:41:18



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-05-02T18:41:11-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c3003591-2231-4850-821b-58e00d9effea'	System	02 May 2021 22:41:18
User entered 'No (N)'	System	02 May 2021 22:41:18

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-05-02T18:41:14-04:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'c3003591-2231-4850-821b-58e00d9effea'	System	02 May 2021 22:41:18
User entered '02 May 2021 18:41:14'	System	02 May 2021 22:41:18

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:11:03



**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:11:03

**US3352072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:11:03
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:11:03



US3352072

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:38:03**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-04T21:09:27-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a9bf13b7-50d6-4b20-8b6e-726b43d63d29'	System	05 Mar 2021 02:18:49
User entered 'No (N)'	System	05 Mar 2021 02:18:49

**US3352072**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDA78881-7CE0-4651-9068-4FB24D8CA3EF)', Time: '2021-03-04T21:09:38-05:00', User OID: 'PatientReportedOutcome (US3352072)', ODM File OID: 'a9bf13b7-50d6-4b20-8b6e-726b43d63d29'	System	05 Mar 2021 02:18:49
User entered '04 Mar 2021 21:09:38'	System	05 Mar 2021 02:18:49

US3352072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 19:39:21

US3352072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 19:39:21

US3352072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Nov 2020 19:39:21

US3352072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 19:39:21

US3352072

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 19:39:24

US3352072

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:27:15
User entered 'I'	System	02 Nov 2020 19:39:24



**US3352072**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	07 Dec 2020 19:43:36

US3352072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '07 Dec 2020'	Rosaidaliz Carreira (b) (4)	07 Dec 2020 19:43:36

US3352072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	07 Dec 2020 19:43:36

US3352072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	Rosaidaliz Carreira (b) (4)	07 Dec 2020 19:43:36

US3352072

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	07 Dec 2020 19:43:40

**US3352072**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User entered 'I'	System	07 Dec 2020 19:43:40

**US3352072**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	04 Jan 2021 18:40:41

US3352072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '4 Jan 2021'	Yulexis Amestoy (b) (4)	04 Jan 2021 18:40:41



US3352072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	04 Jan 2021 18:40:41

US3352072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	Yulexis Amestoy (b) (4)	04 Jan 2021 18:40:41

US3352072

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	04 Jan 2021 18:40:33

**US3352072**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User entered 'I'	System	04 Jan 2021 18:40:33

**US3352072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 18:31:44

US3352072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 18:31:44

**US3352072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Feb 2021 18:31:44

US3352072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:31:44



US3352072

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 18:31:38

US3352072

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:47
User entered 'I'	System	04 Feb 2021 18:31:38

US3352072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:44
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	27 Apr 2021 14:57:26

US3352072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:44
User entered empty.	Rosaidaliz Carreira (b) (4)	27 Apr 2021 14:57:26

US3352072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:44
User entered empty.	Rosaidaliz Carreira (b) (4)	27 Apr 2021 14:57:26

**US3352072**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:03**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	27 Apr 2021 14:57:26

US3352072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:37:09
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:42

**US3352072**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 13:46:42



US3352072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:52

US3352072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '6 Apr 2021'	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:52

US3352072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:52

US3352072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered empty.	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:52

US3352072

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	06 Apr 2021 13:46:57

**US3352072**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 13:46:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:53:53
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you. ' answered with 'LAST SALIVA SAMPLE WAS COLLECTED BY SUBJECT ON 17SEP2020.' (Site from DM).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:07:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:40:37
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 17:51:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 04:12:32
User closed query 'Source indicates subject sat for VS at 10:45. Please add this as time of contact. Consider adding comment explaining this is not the exact start time of visit.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 04:12:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:17:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:17:38
Query 'Source indicates subject sat for VS at 10:45. Please add this as time of contact. Consider adding comment explaining this is not the exact start time of visit.' answered with 'DATA UPDATED ' (Site from CRA).	Wanda Delgado (b) (4)	14 Oct 2020 15:19:59
DataPoint Un-verified.	Wanda Delgado (b) (4)	14 Oct 2020 15:19:48
User entered '10:45' reason for change: Data Entry Error	Wanda Delgado (b) (4)	14 Oct 2020 15:19:48
User opened query 'Source indicates subject sat for VS at 10:45. Please add this as time of contact. Consider adding comment explaining this is not the exact start time of visit.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 16:13:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:40:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 08:57:10
Query 'Data is required. Please complete.' answered with 'time of visit was not captured ' (Site from System).	Wanda Delgado (b) (4)	03 Sep 2020 17:54:09
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:51:24
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 17:51:24



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:58
User entered '21 Aug 2020 10:45'	System	14 Oct 2020 15:19:48
User entered empty.	System	03 Sep 2020 17:51:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:40:37
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Wanda Delgado (b) (4)	03 Sep 2020 17:51:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:19:50
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:40:37
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	03 Sep 2020 17:51:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 1 (Day 1)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (21AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:09:05
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
Query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (21AUG2020) or update accordingly' answered with 'Symptom log updated' (Site from DM).	Sara Gomez (b) (4)	25 Nov 2020 17:06:35
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '19 Aug 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User opened query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (21AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:40:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered '1' reason for change: Data Entry Error	(b) (4) Sara Gomez (b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered empty.	System	03 Sep 2020 19:54:38



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '36.8' C	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:19:34
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:19:34
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:54:38

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 2 (Day 2)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '22 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered '1' reason for change: Data Entry Error	(b) (4) Sara Gomez (b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered empty.	System	25 Nov 2020 16:22:00
User entered '%'	System	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '100.4' F	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
User entered empty; reason for change Data Entry Error	(b) (4)	25 Nov 2020 16:22:00
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:22:00
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:56:57

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 3 (Day 3)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:50:57
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '23 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:45:51
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered '36.8' C reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98.4' F	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:50:54
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:50:59
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:51:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:51:20
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:51:22
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 19:59:18

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 4 (Day 4)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '24 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '96'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:28:49
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '100.4' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98.3' F	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:28:49
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:28:49
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:28:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:01:36

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 5 (Day 5)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '25 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '96'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:33:00
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	03 Sep 2020 20:08:54



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98.4' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98.1' F	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	(b) (4)	
	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	(b) (4)	
	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:33:00
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:30:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:08:54

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 6 (Day 6)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '26 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '96' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '99'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:34:39
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98.3' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98.1' F	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:34:39
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:34:39
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:34:39
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:10:52

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 7 (Day 7)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '27 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '96' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '95'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:35:50
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98.1' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98.1' F	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:35:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:35:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	03 Sep 2020 20:13:44

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 8 (Day 8)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '28 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '99' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:37:10
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:37:10
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98.1' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:37:10
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.2' F	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:37:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:37:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Moderate (Moderate)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:39:56

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 9 (Day 9)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '29 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:04:32
User closed query 'The source note 95-97 and per the guidelines, the lowest saturation is to be recorded. Please consider updating to 95. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:29
Query 'The source note 95-97 and per the guidelines, the lowest saturation is to be recorded. Please consider updating to 95. Thank you.' answered with 'updated' (Site from CRA).	Sara Gomez (b) (4)	16 Dec 2020 16:23:24
DataPoint Un-verified.	(b) (4)	16 Dec 2020 16:23:09
User entered '95' reason for change: New Information	Sara Gomez (b) (4)	16 Dec 2020 16:23:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User opened query 'The source note 95-97 and per the guidelines, the lowest saturation is to be recorded. Please consider updating to 95. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:24:16
User entered '97' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '96'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:39:49
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	04 Sep 2020 12:41:46



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98.1' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97' F	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:39:49
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:39:49
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:39:49
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:41:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 10 (Day 10)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:17:34
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '30 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '96'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:41:11
User entered empty.	System	25 Nov 2020 16:26:01
User entered '%'	System	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.2' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
User entered empty; reason for change Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:26:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.0' F	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:41:11
DataPoint Verified.	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:41:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:43:16

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 11 (Day 11)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:18:17
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:18:17
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '31 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
User entered '96' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '98'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
User entered '97.0' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.1' F	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:42:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:42:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:45:06

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 12 (Day 12)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:18:17
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:18:17
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '1 Sep 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:04:57
User closed query 'Source documents O2 Saturation as 96-97. Per the completion guidelines, the lowest saturation is to be entered into EDC. Please enter 96. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:54
Query 'Source documents O2 Saturation as 96-97. Per the completion guidelines, the lowest saturation is to be entered into EDC. Please enter 96. Thank you.' answered with 'updated' (Site from CRA).	Sara Gomez (b) (4)	16 Dec 2020 16:25:32
DataPoint Un-verified.	(b) (4)	
	Sara Gomez (b) (4)	16 Dec 2020 16:25:18
User entered '96' reason for change: New Information	Sara Gomez (b) (4)	16 Dec 2020 16:25:18
User opened query 'Source documents O2 Saturation as 96-97. Per the completion guidelines, the lowest saturation is to be entered into EDC. Please enter 96. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 17:52:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.0' F	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:46:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 13 (Day 13)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 16:46:14
User entered '31 Aug 2020' reason for change: Per Query Resolution	Sara Gomez (b) (4)	25 Nov 2020 16:46:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 16:46:04
User entered '31 Sep 2020' (non-conformant).	Sara Gomez (b) (4)	25 Nov 2020 16:46:04
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:18:17
User entered '1 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:18:17
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '2 Sep 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
User entered '98' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	04 Sep 2020 12:49:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
User entered '97.1' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.0' F	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 16:45:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:45:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:49:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 14 (Day 14)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:13:06
User closed query 'Per CDM Requery-Response noted,however,under covalascent visit day 28 saliva collection is updated on date 17 sep 2020 ,kindly consider to add another log line for symptoms for the date 17 sep 2020 else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:39:45
User entered '01 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Jan 2021 21:58:36
Query 'Per CDM Requery-Response noted,however,under covalascent visit day 28 saliva collection is updated on date 17 sep 2020 ,kindly consider to add another log line for symptoms for the date 17 sep 2020 else clarify.' answered with 'Convalescent visit was performed 17 sep 2020 and was updated in Illness visit/convalescent visit that include vitals and symptoms and saliva collection same day. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:58:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 21:54:37
User entered '07 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Jan 2021 21:54:37
User opened query 'Per CDM Requery-Response noted,however,under covalascent visit day 28 saliva collection is updated on date 17 sep 2020 ,kindly consider to add another log line for symptoms for the date 17 sep 2020 else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 06:18:32
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 17SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 06:18:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 17SEP2020. Please reconcile or clarify.' answered with 'log updated' (Site from DM).	Sara Gomez (b) (4) (b) (4)	25 Nov 2020 17:07:33
User entered '1 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	25 Nov 2020 16:46:20
DataPoint Un-verified.	Sara Gomez (b) (4) (b) (4)	25 Nov 2020 16:18:17
User entered '2 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4) (b) (4)	25 Nov 2020 16:18:17
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 17SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:40:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '3 Sep 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered '97.0' F	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'Mild (Mild)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:48:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:48:57
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
DataPoint Un-verified.	Sara Gomez (b) (4)	25 Nov 2020 16:48:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:48:57
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:19
User entered 'None (None)'	Wanda Delgado (b) (4)	04 Sep 2020 12:51:02



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 15 (Day 15)' reason for change:	Sara Gomez (b) (4)	25 Nov 2020 16:49:03
Data Entry Error	(b) (4)	
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '02 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:46:36
User entered '03 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:18:28
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:50:28
User entered empty.	System	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.0' F reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 16:50:28
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:18:28

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 16 (Day 16)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '03 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.0' F	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:51:43

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 17 (Day 17)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '04 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.1' F	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:53:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 18 (Day 18)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '05 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.1' F	Sara Gomez (b) (4)	25 Nov 2020 16:54:58
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:54:58



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 19 (Day 19)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '06 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.2' F	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:56:24

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 20 (Day 20)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '07 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.5' F	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'Mild (Mild)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:57:34
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 21 (Day 21)' reason for change:	Sara Gomez (b) (4)	25 Nov 2020 17:00:06
Data Entry Error	(b) (4)	
User entered empty.	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '08 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
User entered '08 Aug 2020'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.2' F	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 16:59:47
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 22 (Day 22)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '09 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.0' F	Sara Gomez (b) (4)	25 Nov 2020 17:04:27



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:04:27
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Day 23 (Day 23)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '10 Sep 2020'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '0'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '98'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User entered '%'	System	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered '97.0' F	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:01
User entered 'None (None)'	Sara Gomez (b) (4)	25 Nov 2020 17:05:17
	(b) (4)	

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 11:25:42
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Data confirmed ' (Site from System).	Wanda Delgado (b) (4)	03 Sep 2020 19:49:11
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Sep 2020 19:48:46
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered 'Nasal Swab (Nasal Swab)'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:11
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:48:46

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:03

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:15
User entered 'I'	System	03 Sep 2020 19:48:46



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12



US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:21
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:40
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 19:51:12

US3352072

Folder: Covid-19 Assessment 21 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:38:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:32:16
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 16:18:00
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:17:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:13:50

**US3352072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 3 (Day 3)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Per GCL Lab recon: Re-query: Saliva: Thank you for confirming the collection date as 24AUG2020. Please consider to update the correct date in EDC for Day 3. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:41:58
Query 'Per GCL Lab recon: Re-query: Saliva: Thank you for confirming the collection date as 24AUG2020. Please consider to update the correct date in EDC for Day 3. Thank you.' answered with 'Saliva for day 3 was collected and dropped off at site on 24/AUG/2020' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:36:05
User entered '24 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	20 Nov 2020 15:35:51
User opened query 'Per GCL Lab recon: Re-query: Saliva: Thank you for confirming the collection date as 24AUG2020. Please consider to update the correct date in EDC for Day 3. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:07:59
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 24AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:07:59
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 24AUG2020. Please reconcile or clarify' answered with 'Day 3 saliva collection was collected on August 24. One day out of window. ' (Site from DM).	Surisaday Mederos (b) (4)	18 Nov 2020 16:42:05
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 24AUG2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 11:22:46
User entered '23 Aug 2020' reason for change: New Information	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered '24 Aug 2020'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 5 (Day 5)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59



US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '25 Aug 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 7 (Day 7)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '27 Aug 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

**US3352072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:38:03**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 9 (Day 9)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '29 Aug 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59



US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 14 (Day 14)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '03 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 21 (Day 21)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '10 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User accepted default value 'Day 28 (Day 28)'	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 14:06:59
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59



US3352072

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 15:43:02
User entered '17 Sep 2020' reason for change: Data Entry Error	Sara Gomez (b) (4)	22 Sep 2020 15:08:51
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 14:06:59

US3352072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:29:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 16:28:06
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:27:48
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:29:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 16:28:08
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:27:48
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:29:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 16:28:09
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:27:48
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:48
User entered 'SICKD1'	System	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '10:50'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18



US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User entered '21 Aug 2020 10:50'	System	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '163.0' cm	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18
DataPoint set to visible.	System	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '72.0' kg	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18
DataPoint set to visible.	System	17 Sep 2020 13:35:03

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '36.8' C	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '59'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User entered 'bpm'	System	17 Sep 2020 13:37:18



US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '15'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User entered 'breaths/min'	System	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '132'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User entered 'mmHg'	System	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:42
User entered '70'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43
User entered 'mmHg'	System	17 Sep 2020 13:37:18

US3352072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43

**US3352072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:43



US3352072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:53
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:36

US3352072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:34:59
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	17 Sep 2020 13:37:36

US3352072

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:38:03

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:19
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:35:11
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 13:41:10

US3352072

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:13:19
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:35:11
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	17 Sep 2020 13:41:10

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:36:29
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 19:07:40

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:36:29
User entered '17 Sep 2020'	Wanda Delgado (b) (4)	17 Sep 2020 19:07:40

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:36:29
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	17 Sep 2020 19:07:40

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered 'SICKD28'	System	17 Sep 2020 19:07:40



US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:38:47
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:38:49
User entered '17 Sep 2020'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:38:52
User entered '14:21'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:35
User entered '163.0' cm	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34
DataPoint set to visible.	System	17 Sep 2020 19:07:40

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:34
User entered '73.0' kg	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34
DataPoint set to visible.	System	17 Sep 2020 19:07:40

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:01
User entered '36.9' C	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:03
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34



US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:39
User entered empty.	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:44
User entered '67'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered 'bpm'	System	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:46
User entered '15'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered 'breaths/min'	System	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:48
User entered '106'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered 'mmHg'	System	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:39:50
User entered '69'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:34



US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User entered 'mmHg'	System	17 Sep 2020 19:08:34

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:40:01
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:48

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:40:04
User entered '17 Sep 2020'	Wanda Delgado (b) (4)	17 Sep 2020 19:08:48

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:38:03

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:40:16
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	17 Sep 2020 19:09:06

US3352072

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:38:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:07
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:40:16
User entered '17 Sep 2020'	Wanda Delgado (b) (4)	17 Sep 2020 19:09:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 17:27:56



US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 17:27:56

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	15 Feb 2021 17:27:56

**US3352072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 17:27:56

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:22

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:22

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06



US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Placebo (Placebo)'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Placebo (Placebo)'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Not Administered (NA)'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'No (N)'	Wanda Delgado (b) (4)	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:38:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User entered '1'	System	15 Feb 2021 17:29:06

**US3352072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:03**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User entered empty.	System	15 Feb 2021 17:29:06

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:08

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 13Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 13Feb21. Please provide accession number and tracking or clarify. Thank you.' answered with 'ACCESSION NUMBER: 1F634464787' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:50:15
	(b) (4), (b) (6)	05 Mar 2021 18:05:57
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 13Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:15:38
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:08



US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13:57'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:08

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User entered '13 Feb 2021 13:57'	System	15 Feb 2021 17:32:08

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:25

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:25

US3352072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User entered '13:45'	Wanda Delgado (b) (4)	15 Feb 2021 17:32:25

**US3352072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:38:03**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:50
User entered '13 Feb 2021 13:45'	System	15 Feb 2021 17:32:25

US3352072

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:38:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Chills, Headache, Muscleaches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:30:43
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Chills, Headache, Muscleaches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'AE was open as a COVID 19 like symptoms, as per CRA the COVID-19 symptoms only apply to illness visits, subject was part of illness visit.' (Site from DM).	Sara Gomez (b) (4) (b) (4)	21 Apr 2021 18:10:42
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Chills, Headache, Muscleaches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:34:27
User closed query 'While the subject has not reported any Concomitant Procedures, please complete the eCRF summary pages as "no". Should new information occur, this page can be updated to "yes" at that time. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:03:37

US3352072

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:38:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'While the subject has not reported any Concomitant Procedures, please complete the eCRF summary pages as "no". Should new information occur, this page can be updated to "yes" at that time. Thank you.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 18:32:14
User opened query 'While the subject has not reported any Concomitant Procedures, please complete the eCRF summary pages as "no". Should new information occur, this page can be updated to "yes" at that time. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:41:28
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:47:39
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	26 Aug 2020 17:54:34
	(b) (4)	



US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:16:54
User entered	System	26 Aug 2020 21:16:45
'USA-US066-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	26 Aug 2020 21:16:45

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:23
Data point term sent to Coder	System	26 Aug 2020 18:29:26
User entered 'Covid 19'	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
Query 'response should be	(b) (4), (b) (6)	08 Nov 2020 22:04:45

eCRF response should be "no" canceled (Site from CRA).

User opened query 'response should be	(b) (4), (b) (6)	29 Oct 2020 18:35:42
---------------------------------------	------------------	----------------------

eCRF response should be "no" (Site from CRA).

User closed query 'Per source, not MAAE. MAAEs are medical visits outside of the study site.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:35:42
--	------------------	----------------------

User entered 'Yes (Y)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:19:17
--	-----------------------	----------------------

Query 'Per source, not MAAE. MAAEs are medical visits outside of the study site.' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	13 Oct 2020 19:16:02
--	-----------------------	----------------------

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:51:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User opened query 'Per source, not MAAE. MAAEs are medical visits outside of the study site.' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 18:48:48
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'No (N)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User closed query 'PV Query: Please clarify if patient began having body aches on 19 Aug (as reported in Tylenol indication). If so, please consider updating start date to date of onset of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:25:27
Query 'PV Query: Please clarify if patient began having body aches on 19 Aug (as reported in Tylenol indication). If so, please consider updating start date to date of onset of symptoms. ' answered with 'Data updated ' (Site from Safety).	Wanda Delgado (b) (4)	13 Oct 2020 19:19:28
DataPoint Un-verified.	Wanda Delgado (b) (4)	13 Oct 2020 19:19:17
User entered '19 Aug 2020' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:19:17
User opened query 'PV Query: Please clarify if patient began having body aches on 19 Aug (as reported in Tylenol indication). If so, please consider updating start date to date of onset of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:53:51
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User closed query 'Per ETRTR: Please complete Covid-19 Assessments Folder and Illness Visit Folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:30:12
Query 'Per ETRTR: Please complete Covid-19 Assessments Folder and Illness Visit Folder, thanks.' answered with 'Data completed ' (Site from CRA).	Wanda Delgado (b) (4)	04 Sep 2020 12:58:26
User opened query 'Per ETRTR: Please complete Covid-19 Assessments Folder and Illness Visit Folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 23:33:27
User entered '21 Aug 2020'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:42:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Dec 2020 16:06:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:06:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Dec 2020 16:05:52
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 16:05:52
User entered '11:11' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 16:05:52
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Aug 2020 18:36:31
User entered empty; reason for change Data Entry Error	Surisaday Mederos (b) (4)	26 Aug 2020 18:36:31
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Aug 2020 18:28:28
User entered '11:11'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28



**US3352072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 16:06:24
User entered '19 Aug 2020 11:11'	System	28 Dec 2020 16:05:52
User entered empty.	System	26 Aug 2020 18:36:31
User entered '21 Aug 2020 11:11'	System	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
Query 'Stop date is noted, but the outcome says ongoing, please update source document. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:37:51
User opened query 'Stop date is noted, but the outcome says ongoing, please update source document. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:34:14
DataPoint Un-verified.	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
User entered 'No (N)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:02:45
User closed query 'Per the symptom log, the first day of no symptoms is 08 Sep 2020. Please consider updating EDC and your AE source doc. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:02:40
Query 'Per the symptom log, the first day of no symptoms is 08 Sep 2020. Please consider updating EDC and your AE source doc. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 15:49:52
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 15:49:52
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User opened query 'Per the symptom log, the first day of no symptoms is 08 Sep 2020. Please consider updating EDC and your AE source doc. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:30:53
DataPoint Un-verified.	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
User entered '04 Sep 2020' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
Query 'Per ETRTR: Please provide the event end date, when available.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:30:39
User opened query 'Per ETRTR: Please provide the event end date, when available.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 22:03:58
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:25:36
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Data updated ' (Site from Safety).	Wanda Delgado (b) (4)	13 Oct 2020 19:19:44
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:53:16
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 20:10:22
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

**US3352072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'No (N)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	



US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	



US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:04:44
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:53:24
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	26 Aug 2020 18:28:28
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 19:39:12
User closed query 'Per CDM re-query: Thank you for your answer. However, please kindly consider entering data under "Dosing discontinuation" form. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:02:53
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Per investigator IP withdrawn due to AE (COVID-19)' (Site from System).	Wanda Delgado (b) (4)	14 Oct 2020 15:22:03
Query 'Per CDM re-query: Thank you for your answer. However, please kindly consider entering data under "Dosing discontinuation" form. Thank you!' answered with 'data updated ' (Site from DM).	Wanda Delgado (b) (4)	14 Oct 2020 15:20:17
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Oct 2020 15:19:13
User opened query 'Per CDM re-query: Thank you for your answer. However, please kindly consider entering data under "Dosing discontinuation" form. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:30:46
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:30:46
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'Subject continuing in trial, however did not receive 2nd vaccine per protocol. ' (Site from DM).	Wanda Delgado (b) (4)	13 Oct 2020 19:21:14

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm rationale for IP Withdrwan, thanks.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 17:18:46
	(b) (4), (b) (6)	10 Sep 2020 18:52:18
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:32:10
Query 'Per ETRTR: Please confirm rationale for IP Withdrwan, thanks.' answered with 'Per protocol subject can not receive the second dose ' (Site from CRA).	Wanda Delgado (b) (4)	04 Sep 2020 13:00:43
User opened query 'Per ETRTR: Please confirm rationale for IP Withdrwan, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 22:08:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User closed query 'Per ETRTR: Please add Medication within Concomitant Medication CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:19:00
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:52:27
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
Query 'Per ETRTR: Please add Medication within Concomitant Medication CRF, thanks.' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	04 Sep 2020 13:00:56
User opened query 'Per ETRTR: Please add Medication within Concomitant Medication CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 23:32:25
User entered 'I'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered '0'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	



US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Source document notes the outcome as ongoing, please update source document. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 15:45:44
Query 'Source document notes the outcome as ongoing, please update source document. Thank you. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 16:06:35
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User opened query 'Source document notes the outcome as ongoing, please update source document. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:38:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:25:48
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Data updated ' (Site from Safety).	Wanda Delgado (b) (4)	13 Oct 2020 19:21:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:15:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:52:33
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 13:58:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User entered empty.	Surisaday Mederos (b) (4)	26 Aug 2020 18:28:28
	(b) (4)	

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:39:19
User closed query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:19:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 18:52:50
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:56
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 22:45:22
User closed query 'PV query: Please confirm if the subject had a positive COVID-19 test. If so, please provide the date test was performed and test type.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 22:45:18
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 22:45:14
User closed query 'PV query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 22:45:10

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'concomitant medication eCRF was updated ' (Site from Safety).	Wanda Delgado (b) (4)	04 Sep 2020 13:18:53
User entered 'SUBJECT CAME INTO THE SITE ON 8/21/2020 COMPLAINING OF COVID-19 SYMPTOMS. SUBJECT WAS TEST AND RESULTS CONFIRMED SUBJECT WAS POSITIVE. SHE STATED SHE TOOK TYLENOL AND MUCINEX DM FOR SYMPTOMS OF COUGH AND BODY ACHES. SYMPTOMS EXHIBITED ARE CHILLS, COUGH, FATIGUE, MUSCLE ACHES, BODY ACHES, HEADACHES,LOSS OF TASTE, LOSS OF SMELL, CONGESTION, RUNNY NOSE, AND DIARRHEA. SUBJECT HAS NOT REQUIRED MEDICAL INTERVENTION NOR SURGICAL TREATMENTS.' reason for change: Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 13:18:32
Query 'PV query: Please confirm if the subject had a positive COVID-19 test. If so, please provide the date test was performed and test type.' answered with 'data UPDATED ' (Site from Safety).	Wanda Delgado (b) (4)	04 Sep 2020 13:15:22
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'DATA UPDATED ' (Site from Safety).	Wanda Delgado (b) (4)	04 Sep 2020 13:15:08

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME INTO THE SITE ON 8/21/2020 COMPLAINING OF COVID-19 SYMPTOMS. SUBJECT WAS TEST AND RESULTS CONFIRMED SUBJECT WAS POSITIVE. SHE STATED SHE TOOK TYLENOL AND MUCINEX DM FOR SYMPTOMS OF COUGH AND BODY ACHES. SYMPTOMS EXHIBITED ARE CHILLS, COUGH, FATIGUE, MUSCLE ACHES, BODY ACHES, HEADACHES, LOSS OF TASTE, LOSS OF SMELL, CONGESTION, RUNNY NOSE, AND DIARRHEA. SUBJECT HAS NOT GONE TO A HOSPITAL FOR MEDICAL CARE.' reason for change: Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 13:14:56
Query 'PV query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Data updated ' (Site from Safety).	Wanda Delgado (b) (4)	04 Sep 2020 13:07:35
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' answered with 'data updated ' (Site from CRA).	Wanda Delgado (b) (4)	04 Sep 2020 13:07:17
User entered 'Subject came into the site on 8/21/2020 complaining of COVID-19 symptoms. Subject was test and results confirmed subject was positive. she stated she took Tylenol and Mucinex DM for symptoms. Subject has not gone to a hospital for medical care.' reason for change: Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 13:06:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 13:59:18

US3352072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please confirm if the subject had a positive COVID-19 test. If so, please provide the date test was performed and test type.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 13:59:04
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 13:58:50
User opened query 'PV query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 13:57:28
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 23:30:23
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	26 Aug 2020 18:28:28

**US3352072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Aug 2020 18:28:28

**US3352072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 19:19:17
User entered '0'	System	13 Oct 2020 19:15:35
User entered '1'	System	26 Aug 2020 18:28:28



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:38:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:03:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:08:01
User closed query 'Per DM CLR: Per Diary Dose 1 Day 8, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:07:58
Query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Data updated ' (Site from DM).	Wanda Delgado (b) (4)	23 Nov 2020 17:50:31
Query 'Per DM CLR: Per Diary Dose 1 Day 8, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Data updated' (Site from DM).	Wanda Delgado (b) (4)	23 Nov 2020 17:50:18

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:38:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever &gt; 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:37:56
User opened query 'Per DM CLR: Per Diary Dose 1 Day 8, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:00:32
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:01
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	04 Sep 2020 12:54:14

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:52:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 12:57:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 12:57:45
Data point term sent to Coder	System	04 Sep 2020 12:56:44
User entered 'Tylenol'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:53:26
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:53:27
User entered 'body aches (due to covid-19)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:42
User closed query 'Con-Med source indicates Dose = 500 PRN, however, EDC indicates dose = 1000. Please verify dose per administration and update source or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:36:38
Query 'Con-Med source indicates Dose = 500 PRN, however, EDC indicates dose = 1000. Please verify dose per administration and update source or EDC as applicable.' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	13 Oct 2020 19:24:29
User entered '500' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:24:18
User opened query 'Con-Med source indicates Dose = 500 PRN, however, EDC indicates dose = 1000. Please verify dose per administration and update source or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 16:55:37
User entered '1000' reason for change: Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 14:02:22
User entered '500'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:15
User entered 'mg (mg)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:19
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:03:11
User entered 'as needed (PRN)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:20
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:02:52
User entered 'Oral (ORAL)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:25
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:59
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (21AUG2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM start date.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:21:52
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (21AUG2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM start date.' answered with 'COVID 19 AE updated ' (Site from DM).	Wanda Delgado (b) (4)	13 Oct 2020 19:24:13
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (21AUG2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM start date.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 10:27:19
User entered '19 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:45
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:47
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:00:51
User entered '28 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:03

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:37:18
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' answered with 'Medication was taken for symptom related to COVID-19' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:38:43
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:02:43
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:56:34

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:56:34

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:56:34

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:56:34

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 12:59:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 12:59:37
Data point term sent to Coder	System	04 Sep 2020 12:58:48
User entered 'Mucinex'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'cough (due to covid-19)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '600' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:27:49
User entered '1'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g.,4100 mg, 600 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:23:27
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g.,4100 mg, 600 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Data updated ' (Site from DM).	Wanda Delgado (b) (4)	13 Oct 2020 19:28:01
User entered 'mg (mg)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	13 Oct 2020 19:27:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g.,4100 mg, 600 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 10:27:42
User entered 'tablet (TABLET)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'as needed (PRN)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'Oral (ORAL)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '27 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '0'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '31 Aug 2020'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	04 Sep 2020 12:57:50

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User entered empty.	System	04 Sep 2020 12:57:50

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User entered empty.	System	04 Sep 2020 12:57:50

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:46
User entered empty.	System	04 Sep 2020 12:57:50

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:58:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:58:03
Data point term sent to Coder	System	23 Nov 2020 17:52:45
User entered 'tylenol'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:25:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'did not meet the AE reporting criteria' (Site from DM).	Matthew Muniz (b) (4)	12 Jan 2021 19:50:42

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:52:03
	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'headache'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '500'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'mg (mg)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'as needed (PRN)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'Oral (ORAL)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57



US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered empty.	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '19 Aug 2020'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '0'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered '28 Aug 2020'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:00:00
User entered 'No (N)'	Wanda Delgado (b) (4)	23 Nov 2020 17:51:57

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User entered empty.	System	23 Nov 2020 17:51:57

US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User entered empty.	System	23 Nov 2020 17:51:57



US3352072

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:47
User entered empty.	System	23 Nov 2020 17:51:57

US3352072

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:38:03**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:03:48
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 18:31:46

US3352072

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:03

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:41:41
User entered '21 Aug 2020'	Wanda Delgado (b) (4)	14 Oct 2020 15:19:13

US3352072

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:03

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:41:41
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to updatethe necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:15:36
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to updatethe necessary eCRFs required else clarify.' answered with 'AS PER PROTOCOL SUBJECTS THAT TEST POSITIVE WILL CONTINUE WITH STUDY UNTIL THE END FOR SAFETY REASON BUT DO NOT RECIEVE THE SECOND VACCINE.' (Site from DM).	Rosaidaliz Carreira (b) (4)	14 Nov 2020 18:37:55
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to updatethe necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:55:37
User entered 'Due to SARS-COV-2 (COVID)'	Wanda Delgado (b) (4)	14 Oct 2020 15:19:13

US3352072

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:03

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:41:41
User entered empty.	Wanda Delgado (b) (4)	14 Oct 2020 15:19:13

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:25:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'USA-US066-2020-MRNA-1273-P301000001'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:27:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:26:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:33
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:22:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45



**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:20
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Howard'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:23
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'schwartz'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '7265 SHeridan Street SUite 210'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:27
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Pembroke Pines'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:28
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:30
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '33024'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:02:32
Un-reviewed for Safety.	System	07 Sep 2020 22:45:52
User entered 'US' (non-conformant).	System	07 Sep 2020 22:45:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 22:45:40
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 12:52:20
User entered 'US' (non-conformant).	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Oct 2020 15:43:14
User entered '2'	System	07 Sep 2020 22:45:52
User entered '1'	System	26 Aug 2020 21:18:10

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:25:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'USA-US066-2020-MRNA-1273-P301000001'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:27:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:26:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:33
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:22:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:20
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Howard'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:23
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'schwartz'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '7265 SHeridan Street SUite 210'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:27
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Pembroke Pines'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:28
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:30
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '33024'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:02:32
Un-reviewed for Safety.	System	07 Sep 2020 22:45:52
User entered 'US' (non-conformant).	System	07 Sep 2020 22:45:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 22:45:40
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 12:52:20
User entered 'US' (non-conformant).	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Oct 2020 15:43:14
User entered '2'	System	07 Sep 2020 22:45:52
User entered '1'	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:38:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
User entered '26/Aug/2020 17:18'	System	26 Aug 2020 21:18:10

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:38:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 22:45:40
User entered 'l'	(b) (4), (b) (6)	26 Aug 2020 21:18:10

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:25:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'USA-US066-2020-MRNA-1273-P301000001'	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:27:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:26:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:33
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:22:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:20
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Howard'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:23
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'schwartz'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '7265 SHeridan Street SUite 210'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:27
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Pembroke Pines'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:28
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:30
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '33024'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:02:32
Un-reviewed for Safety.	System	07 Sep 2020 22:45:52
User entered 'US' (non-conformant).	System	07 Sep 2020 22:45:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 22:45:40
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 12:52:20
User entered 'US' (non-conformant).	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Oct 2020 15:43:14
User entered '2'	System	07 Sep 2020 22:45:52
User entered '1'	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:38:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
User entered '07/Sep/2020 18:45'	System	07 Sep 2020 22:45:52



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:38:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 22:45:52

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:25:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'USA-US066-2020-MRNA-1273-P301000001'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:27:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:26:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:33
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:22:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45



US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:37:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:20
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered 'No (N)'	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Howard'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:23
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'schwartz'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '7265 SHeridan Street SUite 210'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:27
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'Pembroke Pines'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:28
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:30
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:21
Amendment Manager: User entered '33024'	System	14 Sep 2020 21:51:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 21:18:02
User entered (b) (6)	System	26 Aug 2020 21:16:45

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:23:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:02:32
Un-reviewed for Safety.	System	07 Sep 2020 22:45:52
User entered 'US' (non-conformant).	System	07 Sep 2020 22:45:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 22:45:40
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	04 Sep 2020 12:52:20
User entered 'US' (non-conformant).	System	26 Aug 2020 21:18:10



**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Oct 2020 15:43:14
User entered '2'	System	07 Sep 2020 22:45:52
User entered '1'	System	26 Aug 2020 21:18:10

**US3352072**

**Folder: SAE USA-US066-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:38:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
User entered '14/Oct/2020 15:43'	System	14 Oct 2020 15:43:14

US3352072

Folder: SAE USA-US066-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:38:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:40:18
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 15:43:14